

Exhibit 83

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

IN RE:

FOLEY V. AVON PRODUCTS, INC. ET AL.	MID-L-3095-18 AS
FRACE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-600-18 AS
GATMAITAN V. IMERYS TALC AMERICA, ET AL.	MID-L-4252-18 AS
GRABOWSKI V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-6805-16 AS
GREENE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-2456-18 AS
GRIFFIN V. CYPRUS AMAX MINERALS COMPANY, ET AL.	MID-L-4826-18 AS
HODJERA V. BORGWARNER MORSE TEC, LLC, ET AL.	MID-L-5368-17 AS
MCNEILL-GEORGE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-7049-16 AS
SELVAGGIO V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-598-18 AS
WENDOWSKI V. IMERYS TALC AMERICA, INC., ET AL.	MID-L-6635-17 AS

VIDEOTAPE DEPOSITION OF SUSAN NICHOLSON, MD

Transcript of the deposition of the witness,
called for Oral Examination in the above-captioned
matter, said deposition being taken pursuant to
Superior Court Rules of Practice and Procedure by and
before MARC BRODY, a Notary Public and Certified
Court Reporter of the State of New Jersey, at the law
offices of DRINKER, BIDDLE & REATH, 105 College Road East,
Princeton, New Jersey, on Tuesday, February 19, 2019,
commencing at approximately 10:00 in the forenoon.

BRODY DEPOSITION SERVICES
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Westfield, New Jersey 07090

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Brody Deposition Services

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<p>1 APPEARANCES:</p> <p>2</p> <p>3 COHEN, PLACITELLA & ROTH, P.C.</p> <p>4 127 Maple Avenue</p> <p>5 Red Bank, New Jersey 07701</p> <p>6 732-747-9003</p> <p>7 BY: CHRISTOPHER PLACITELLA, ESQ.</p> <p>8 AND: DENNIS GEIER, ESQ.</p> <p>9 Attorneys for Plaintiff</p> <p>10</p> <p>11 RAWLE & HENDERSON, LLP (Via speakerphone)</p> <p>12 1339 Chestnut Street, 16th floor</p> <p>13 Philadelphia, Pennsylvania 19107</p> <p>14 215-575-4200</p> <p>15 BY: ANISHA S. ABRAHAM, ESQ.</p> <p>16 Attorneys for Defendants, Imerys Talc,</p> <p>17 Cyprus Amax Minerals</p> <p>18</p> <p>19 McGIVNEY, KLUGER & COOK, P.C. (Via speakerphone)</p> <p>20 18 Columbia Turnpike, 3rd floor</p> <p>21 Florham Park, New Jersey 07932</p> <p>22 973-822-1110</p> <p>23 BY: ELIZABETH BARNA, ESQ.</p> <p>24 Attorneys for Defendant, Whittaker, Clark &</p> <p>25 Daniels</p> <p>26</p> <p>27 BLANK ROME, LLP</p> <p>28 One Logan Square</p> <p>29 Philadelphia, Pennsylvania 19103</p> <p>30 215-569-5397</p> <p>31 BY: REBECCA D. WARD, ESQ.</p> <p>32 AND: JAMES T. SMITH, ESQ.</p> <p>33 Attorneys for Defendant, Johnson & Johnson</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p> <p>39</p> <p>40</p> <p>41</p> <p>42</p> <p>43</p> <p>44</p> <p>45</p>	<p>1 INDEX</p> <p>2 WITNESS PAGE</p> <p>3 SUSAN NICHOLSON, MD</p> <p>4 Direct by Mr. Placitella 5</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11 EXHIBITS</p> <p>12 NO. DESCRIPTION PAGE</p> <p>13 P-1 Deposition Notice 5</p> <p>14 P-2 5 pages of notes by S. Nicholson 10</p> <p>15 P-3 Notebook of J&J Documents 54</p> <p>16 P-4 Notebook of J&J Documents 54</p> <p>17 P-5 Notebook of J&J Documents 54</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 Note: ALL DOCUMENTS REFERRED TO DURING DEPOSITION</p> <p>23 ARE LISTED ON PAGES 201-202.</p> <p>24</p> <p>25</p> <p>26</p> <p>27</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p>
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<p>1 APPEARANCES (Cont'd):</p> <p>2</p> <p>3 O'TOOLE, FERNANDEZ, WEINER & (Via speakerphone)</p> <p>4 VAN LIEU</p> <p>5 14 Village Park Road</p> <p>6 Cedar Grove, New Jersey 07009</p> <p>7 973-239-5700</p> <p>8 BY: LESLIE LOMBARDY, ESQ.</p> <p>9 Attorneys for Defendant, Colgate-Palmolive</p> <p>10</p> <p>11 ALSO PRESENT:</p> <p>12 Carolyn McNelis, Paralegal, Cohen Placitella & Roth, PC</p> <p>13 Erik Davidson, Videographer, Dynamic Evidence</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 MR. PLACITELLA: Mark this P-1.</p> <p>2 (The above notice is marked P-1.)</p> <p>3</p> <p>4 THE VIDEOGRAPHER: We are now on the</p> <p>5 record. My name is Erik Davidson representing</p> <p>6 Dynamic Evidence. The date is Tuesday, February 19,</p> <p>7 2019 and the time is approximately 10:00 a.m. The</p> <p>8 appearances will be noted on the stenographic</p> <p>9 record.</p> <p>10 Our court reporter, Marc Brody, will now</p> <p>11 swear in the witness.</p> <p>12</p> <p>13 SUSAN NICHOLSON, sworn.</p> <p>14</p> <p>15 DIRECT EXAMINATION BY MR. PLACITELLA:</p> <p>16</p> <p>17 Q Good morning, Dr. Nicholson, how are you?</p> <p>18 A Good thanks. Good morning.</p> <p>19 Q You are a doctor by training. Is that</p> <p>20 correct?</p> <p>21 A Yes, a medical doctor.</p> <p>22 Q When did you graduate medical and from</p> <p>23 where?</p> <p>24 A 1992 from the University of</p> <p>25 Pittsburgh.</p>

<p style="text-align: right;">Page 6</p> <p>1 Q Am I correct that you have never, as a 2 medical doctor, you have never seen any actual 3 patients? 4 A That's not correct. 5 Q When is the last time you actually saw a 6 patient as a medical doctor? 7 A I don't have a precise date. For ten 8 years I was a rounding consulting physician at 9 Cornell New York Hospital in New York City, and my 10 activities petered out -- I probably haven't seen a 11 patient in ten years. 12 Q You started at Johnson and Johnson in 13 2006. Is that correct? 14 A That's correct. 15 Q In what capacity? 16 A As a senior director in clinical research 17 in our pharmaceutical division. 18 Q Did you ever have any personal interaction 19 with the FDA concerning the issue of asbestos and 20 talc? 21 A No, I didn't. 22 Q Am I correct you have no training in 23 geology? 24 A That's correct. 25 Q And you are not an expert in testing talc</p>	<p style="text-align: right;">Page 8</p> <p>1 Q And the documents you reviewed, 2 specifically are what? 3 A I reviewed documents specifically going 4 back and forth between Johnson and Johnson to the 5 FDA, the FDA back to Johnson and Johnson and 6 documents from the industry group CTFA, now PCPC 7 relating to talc and asbestos testing as they were 8 acting on behalf of the industry as general 9 background, and also some of the contextual 10 documents for those decades. It has been 50 years 11 of communications and an evolution of science, so 12 some contextual documents were necessary to 13 understand the context. 14 Q Am I correct that those documents are with 15 you today? 16 A They are. 17 Q We will mark them at a break so not to 18 take up any time. 19 Am I correct that you are not the 20 author or the recipient of any of the documents in 21 these books? 22 A I'm not specifically, no. 23 Q So you were the person designated on 24 behalf of the Johnson and Johnson to speak for the 25 company, but you have no personal knowledge of any</p>
<p style="text-align: right;">Page 7</p> <p>1 for asbestos? 2 A I'm not. 3 Q You have in front of you P-1, which is the 4 deposition notice for today. The deposition notice 5 calls for Johnson and Johnson to produce a corporate 6 representative with the most knowledge concerning 7 testing information provided to the Food and Drug 8 Administration by Johnson and Johnson concerning the 9 asbestos content of cosmetic talc, and any responses 10 from the FDA in relation thereto. Do you see that? 11 A Yes, I do. 12 Q Why are you the person most qualified? 13 A I'm the person most qualified because I've 14 reviewed all of the documents related to the 15 communications back and forth between the FDA 16 starting in the late '60s up until the present. 17 I have interviewed and interacted 18 with the individuals who currently do the testing, 19 people who are involved historically with the 20 testing, so I understand what was communicated and 21 how the testing methodology evolved over time. 22 Q Any people still work for Johnson and 23 Johnson who were involved in communicating with the 24 FDA concerning the testing for asbestos in talc? 25 A Not that I'm aware of, no.</p>	<p style="text-align: right;">Page 9</p> <p>1 of the evidence you brought with you today? 2 A That's not correct. I didn't say that. I 3 was involved in more contemporary communications and 4 discussions about communications with the FDA, but 5 your question previously was about whether or not 6 they were to me specifically or from me 7 specifically. That answer is no. 8 But I was involved in discussions 9 related to the communications. 10 Q Have you communicated yourself with the 11 FDA either in writing or verbally? 12 A I was at a meeting in June of last year 13 with a group of individuals from Johnson and Johnson 14 and the FDA to discuss the quality systems and 15 methods for testing asbestos. 16 Q June 19, 2018? 17 A Correct. 18 Q You said you interviewed. By the way, who 19 made the determination as to what documents you were 20 going to review in preparation for today's 21 deposition? 22 A The attorneys assisted in searching the 23 database. It is quite a large and extensive 24 database for FDA communications related to the 25 request for today.</p>

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<p>1 Q So the lawyers made the decision what 2 documents you were going to review? 3 A The actual communications, yes. With 4 regard to context, we discussed that and 5 collaborated on which documents were most relevant. 6 Q Now, you said you interviewed people in 7 connection with today's deposition. Who was that? 8 A I'm going to refer to my notes here, if 9 you don't mind. 10 Q Sure. 11 MR. PLACITELLA: Why don't we just 12 mark your notes as P-2. 13 (Dr. Nicholson's notes are marked 14 P-2.) 15 Q Why don't you describe what P-2 is. 16 A P-2 are a number of notes during 17 preparation for today. It is a lot of information 18 and I wanted to organize my thinking by decades, 19 '60s, '70s, '80s, '90s, 2000s and 2010 to current. 20 In addition, I made some notations 21 about individuals that I would speak to about 22 various topics, and just some contextual notes for 23 my own -- a memoir, if you will. 24 Q So who are the people you spoke with? 25 A That's what where I was headed. I spoke</p>	<p>1 A Previous conversations I've had with John 2 Hopkins and Don Hicks. Don Hicks is a director of 3 quality. He since retired. 4 Q Did John Hopkins have any dealing with the 5 FDA to your knowledge? 6 A Yes. He started with the company in 1976 7 and retired in 2000. 8 Q You know for a fact he spoke with the FDA 9 about the issue of asbestos and testing? 10 A He and I discussed communications back and 11 forth. I don't know that he actually was the person 12 speaking on any given case, but he had the 13 historical knowledge. 14 Q But do you know whether or not he had any 15 personal involvement with the FDA? 16 A I believe he did, yes. 17 Q Now, anybody else? 18 A Not that I recall. 19 Q I want to talk to you about what Johnson 20 and Johnson understands or understood historically 21 its role was as it related to communications with 22 the FDA. 23 Am I correct that Johnson and Johnson 24 understands that cosmetic talc does not require 25 premarket approval from the FDA?</p>
Page 11	Page 13
<p>1 to Linda Szczepaniak. 2 Q Spell that for the reporter and me. 3 A I wish I could. S C Z and the rest is we 4 will have to -- P H O N I K, maybe. 5 Q What was her job? 6 A Global head of regulatory affairs for our 7 consumer division. 8 Q For what period of time? 9 A I don't know when she started. At least 10 four years. 11 Q Currently? 12 A That's correct. Currently. 13 Q Who else? 14 A Bobbette Williams. 15 Q Bobbette? 16 A Williams. 17 Q And what is her job? 18 A She's Vice-President in our quality group. 19 Q Okay. Who else? 20 A I spoke to Tim McCarthy who has been with 21 the company a number of years. He is a 22 toxicologist. 23 Q Is he still with the company? 24 A He is. 25 Q Who else?</p>	<p>1 A Yes. 2 Q Am I correct that the FDA promulgated 3 regulations that remain in effect today followed by 4 Johnson and Johnson that require each ingredient 5 used in cosmetic product, any finished cosmetic 6 product be adequately substantiated for safety prior 7 to marketing? 8 MR. SMITH: Objection. 9 A Yes, we are aware of that. 10 Q And is Johnson and Johnson further aware 11 that the regulations state that any ingredient or 12 product whose safety is not adequately substantiated 13 prior to marketing, is misbranded unless it contains 14 the following conspicuous statement on the principal 15 display panel. "Warning, the safety of this product 16 has not been determined." 17 MR. SMITH: Objection. 18 Q Are you aware of that? 19 MR. SMITH: Could I just ask you to 20 put a little pause in there before you answer so I 21 can pipe in once in a while and earn my fee? 22 A Yes. 23 Q Johnson and Johnson understood that a 24 manufacturer who has not adequately substantiated 25 the safety of their cosmetic product or their</p>

<p style="text-align: right;">Page 14</p> <p>1 ingredients cannot ship their product in interstate 2 commerce? 3 MR. SMITH: Objection. 4 A Yes. 5 Q In addition, a manufacturer of a cosmetic 6 product must assure that the cosmetic label shall 7 bear a warning statement whenever necessary or 8 appropriate to prevent a health hazard that may be 9 associated with the product? 10 MR. SMITH: Objection. 11 A Yes. 12 Q Johnson and Johnson understands that the 13 regulations require that an ingredient or product 14 having a history of use in or as a cosmetic may at 15 any time have its safety brought into question by 16 new information that in and of itself is not 17 conclusive? 18 MR. SMITH: Objection. 19 A I don't know what that means. 20 Q It is not proven beyond more probable than 21 not. Just the risk is there. 22 A Can you repeat? 23 Q Sure the regulations require that an 24 ingredient or product having a history of use as a 25 cosmetic may at any time have its safety brought</p>	<p style="text-align: right;">Page 16</p> <p>1 the scope. 2 MR. PLACITELLA: You can make that 3 objection. I think it is not proper, but you can 4 make it. If you have a form objection, that's what 5 is permitted. You can raise scope with the judge. 6 I think it is clearly within the scope. 7 MR. SMITH: Again, I know we are not 8 going to figure that out today. I want to make sure 9 we are all on the same page. Do you want me to put 10 the basis for the objection on the record? 11 MR. PLACITELLA: That's fine, the way 12 you are -- 13 MR. SMITH: Just objection preserves 14 everything so we can keep -- 15 MR. PLACITELLA: Fair enough. 16 17 Q Johnson and Johnson understands that a 18 cosmetic is considered adulterated if it bears or 19 contains any poisonous or deleterious substance 20 which may render it injurious to users? 21 MR. SMITH: Objection. 22 A Yes. 23 Q Johnson and Johnson understands that 24 information provided to the FDA concerning the 25 testing of Johnson and Johnson talc is voluntary,</p>
<p style="text-align: right;">Page 15</p> <p>1 into question by new information that in itself is 2 not conclusive? 3 MR. SMITH: Objection. 4 Q You understood that? 5 A I understand that. I didn't understand. I 6 hear you, but that last piece, I'm not sure what 7 that means. 8 But let me just say we do understand 9 that the safety of products are overseen on a 10 continuous basis, and if there's new information 11 that comes in, that calls into question the safety 12 of a product that, yes, we are obligated to research 13 that, understand it, determine if there's been any 14 change in the safety profile that's actionable, if 15 that's your question, yes. 16 MR. SMITH: While there's no question 17 bending, let me put on the record my understanding, 18 as we discussed before we started the deposition 19 with opposing counsel, placing the word objection on 20 the record preserves all bases? 21 MR. PLACITELLA: You could say 22 objection to form, if that is your objection. 23 MR. SMITH: I'm objecting to beyond 24 the scope. This witness is here as a 30(b)6. She 25 is being asked questions that in my view are outside</p>	<p style="text-align: right;">Page 17</p> <p>1 correct? 2 MR. SMITH: Objection. 3 A Yes. 4 Q Johnson and Johnson understands that 5 without a regulation, the FDA has no authority to 6 require information on safety testing related to 7 talc from Johnson and Johnson, correct? 8 MR. SMITH: Objection. 9 A I'm not sure that's correct. If the FDA 10 has a concern about safety and they ask us for 11 information, I believe we are obligated to give it 12 to them. 13 Q Okay. Johnson and Johnson understands now 14 and historically that the FDA only has very limited 15 resources to commit to cosmetic product review, 16 monitoring or safety? 17 MR. SMITH: Objection. 18 A I can't speak to the resources of the FDA. 19 Q Have you looked at documents that in fact 20 indicate that the FDA has limited resources on the 21 issue of talc testing and asbestos? You are aware 22 of that, aren't you? 23 A I know there's one document that makes 24 reference to that at a point in time about a very 25 extensive testing program that was discussed. I</p>

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<p>1 don't think that's a general statement that's 2 applicable to the FDA. 3 Q So it is your position that the FDA has 4 more than adequate resources to do its own testing 5 of the Johnson and Johnson talc for asbestos? 6 MR. SMITH: Objection. 7 A I'm not in a position to comment on the 8 FDA's resources. 9 Q Does Johnson and Johnson agree that the 10 FDA regulatory authority over cosmetics is less 11 comprehensive than over food and drugs? 12 MR. SMITH: Objection. 13 A I'm aware of that, yes. 14 Q Does Johnson and Johnson understand that 15 in its oversight of the cosmetic industry, the FDA 16 must rely on part on voluntary industry cooperation? 17 MR. SMITH: Objection. 18 A Yes, I understand that. 19 Q Does Johnson and Johnson understand that 20 the FDA does not have authority to require Johnson 21 and Johnson to do safety testing and provide injury 22 reports concerning its talc? 23 MR. SMITH: Objection. 24 A I can't agree that we understand that in 25 totality. If the FDA made a specific request for</p>	<p>1 Q And is that something that was established 2 by the cosmetic trade association as far back as 3 1976? 4 A I don't remember the specific historical 5 details. 6 Q You don't know who was responsible for 7 forming the CIR? 8 A Exactly. 9 Q Or what entity? 10 A Exactly, no, I'm not. 11 Q Do you know that the CIR is an industry 12 funded panel that reviews the safety of ingredients 13 used in cosmetic talc? 14 MR. SMITH: Objection. 15 A I know they get funding from the industry, 16 yes. 17 Q Am I correct that the purpose of the CIR 18 is to determine cosmetic ingredients for which 19 there's reasonable certainty in the judgment of 20 competent scientists that the ingredient is safe 21 under the conditions of use? 22 MR. SMITH: Objection. 23 A Yes. 24 Q Has the CIR in fact stated that safe or 25 safety means there's no evidence in the available</p>
Page 19	Page 21
<p>1 information, I believe we would be obligated to 2 respond to it. 3 We don't regularly and routinely 4 share safety information with the FDA, unless it is 5 required, or we feel that it is important and 6 helpful. 7 Q Does Johnson and Johnson agree that a 8 cosmetic manufacturer has a responsibility to 9 substantiate the safety of their product or they 10 must warn consumers the safety of the product has 11 not been determined? 12 MR. SMITH: Objection. 13 A Yes. 14 Q Does Johnson and Johnson understand that 15 if there's a health hazard associated with the product, 16 it must include a warning on that product? 17 MR. SMITH: Objection. 18 A Yes. 19 Q Do you know what the Cosmetic Ingredient 20 Review or CIR is? 21 A Yes. 22 Q What is that? 23 A The Cosmetic Ingredient Review is a 24 process and a system essentially of reviewing the 25 safety of cosmetic ingredients.</p>	<p>1 information that demonstrates or suggests reasonable 2 grounds to suspect a hazard to the public under the 3 conditions of use that are now current or that might 4 reasonably be expected in the future? 5 MR. SMITH: Objection. 6 A I can't answer that because I haven't 7 reviewed CIR's definitions as of the recent 8 past. 9 Q How much work did you do in reference to 10 the CIR to prepare for today's deposition? 11 A None. 12 Q None at all? 13 A No. 14 Q Does Johnson and Johnson agree that it has 15 a responsibility to assure that there's reasonable 16 certainty there's no evidence to suspect that their 17 cosmetic talc products may cause any harm to the 18 consumer? 19 MR. SMITH: Objection. 20 A Could you repeat that? 21 Q Does Johnson and Johnson recognize it has 22 a responsibility to assure that there's reasonable 23 certainty that there is no evidence to suspect that 24 their cosmetic talc products may cause harm to the 25 consumer?</p>

Page 22	Page 24
<p>1 MR. SMITH: Objection.</p> <p>2 A Yes.</p> <p>3 Q Does Johnson and Johnson recognize that if</p> <p>4 there is evidence that there are reasonable grounds</p> <p>5 to suspect that the cosmetic talc product may cause</p> <p>6 harm for the proposed use, such product does not</p> <p>7 meet industry standards for safety?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes.</p> <p>10 Q Does Johnson and Johnson recognize that</p> <p>11 talc with asbestiform fibers are recognized as known</p> <p>12 human carcinogens?</p> <p>13 MR. SMITH: Objection.</p> <p>14 A Asbestos is a known carcinogen, yes.</p> <p>15 Q And Johnson and Johnson recognizes that if</p> <p>16 asbestos or asbestiform fibers are found in the</p> <p>17 talcum powder products, those products would be</p> <p>18 adulterated under the Federal Food Drug and Cosmetic</p> <p>19 Act?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A To clarify, if there's asbestos in talc,</p> <p>22 yes, I would agree.</p> <p>23 Q Am I correct, and I asked you this before,</p> <p>24 but I want to tease it out a little bit. Is it</p> <p>25 Johnson and Johnson's position that it is not aware</p>	<p>1 numbers.</p> <p>2 MR. PLACITELLA: It was given to me</p> <p>3 by Dr. Hopkins in his deposition. It was marked</p> <p>4 at his deposition as D-12, so that's your issue.</p> <p>5 Q Do you see where it talks about a program,</p> <p>6 the first thing says cosmetics. Do you see that?</p> <p>7 A Yes.</p> <p>8 Q If you flip through it, you see that it</p> <p>9 refers to multiple years and multiple projects. Do</p> <p>10 you see that?</p> <p>11 A I do.</p> <p>12 Q I'm going to refer you to the entry for</p> <p>13 1976. I'll blow it up for you. Under the project</p> <p>14 titled Determination of Asbestos in Talc. Do you</p> <p>15 see that?</p> <p>16 MR. SMITH: What page are we on,</p> <p>17 Counsel?</p> <p>18 A I need to look at it.</p> <p>19 Q Your pages aren't numbered, unfortunately.</p> <p>20 MR. SMITH: Some are.</p> <p>21 Q Project number 00679.</p> <p>22 MR. SMITH: There are multiple pages</p> <p>23 with that project.</p> <p>24 Q There are multiple pages and I'm on the</p> <p>25 page that talks about description of this quarter's</p>
Page 23	Page 25
<p>1 that FDA has limited resources when it comes to</p> <p>2 testing cosmetic talc for asbestos?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A I can't speak to the FDA'S resources.</p> <p>5 Q Do you know who John Stuart is, who worked</p> <p>6 at the FDA?</p> <p>7 A I don't recall off the top of my head, no.</p> <p>8 The name sounds familiar, but I don't remember</p> <p>9 exactly.</p> <p>10 Q Do you know that John Stuart left the FDA</p> <p>11 in 1976?</p> <p>12 A No.</p> <p>13 Q Do you know that when John Stuart left the</p> <p>14 FDA, there was no one at FDA any experience in</p> <p>15 testing talc for asbestos?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A I can't speak to FDA'S expertise or</p> <p>18 resources.</p> <p>19 Q D-12 is a document from 1975 that was</p> <p>20 provided to me by Dr. Hopkins at his deposition.</p> <p>21 Has Dr. Hopkins shared this document with you?</p> <p>22 A I don't recall seeing this. It refers to</p> <p>23 aerosols and hair preparations.</p> <p>24 MR. SMITH: Counsel, while there's no</p> <p>25 question pending, this document doesn't have Bates</p>	<p>1 activities, and the first paragraph stating, the</p> <p>2 purpose of this project is to develop one or several</p> <p>3 methods for sufficient sensitivity and reliability</p> <p>4 which will permit the determination of asbestos and</p> <p>5 other contaminants in talc-containing products with</p> <p>6 the necessary degree of accuracy and at a</p> <p>7 concentration at which such contaminants present a</p> <p>8 potential health hazard. Do you see that?</p> <p>9 MR. SMITH: I don't.</p> <p>10 A Yes.</p> <p>11 Q When you met with, when you spoke with Dr.</p> <p>12 Hopkins, he didn't discuss any of these reports with</p> <p>13 you, even though they refer directly to the FDA --</p> <p>14 MR. SMITH: Objection.</p> <p>15 Q In testing of asbestos?</p> <p>16 A Let me point out, number one, that this</p> <p>17 starts with aerosols and hair preparations. Number</p> <p>18 two, this doesn't look like a communication to or</p> <p>19 from Johnson and Johnson to the FDA, so I did not</p> <p>20 review that in preparation for today. And this is a</p> <p>21 bit of a confusing document. I'm not exactly sure</p> <p>22 what we are supposed to focus on since every page</p> <p>23 seemed to be marked project 679.</p> <p>24 Q What we are focusing on the page that</p> <p>25 talks about the determination of asbestos in talc.</p>

<p style="text-align: right;">Page 26</p> <p>1 A Yes, I realize that.</p> <p>2 Q And what is listed in this document, and</p> <p>3 this came from Johnson and Johnson. I didn't get it</p> <p>4 on my own. You understand that, right?</p> <p>5 A That's fair. I'm just trying to find the</p> <p>6 page you are on.</p> <p>7 MR. SMITH: In fairness, I don't know</p> <p>8 that it came from Johnson and Johnson.</p> <p>9 MR. PLACITELLA: You don't know?</p> <p>10 MR. SMITH: It doesn't have Johnson</p> <p>11 and Johnson Bates numbers on it.</p> <p>12 MR. PLACITELLA: Mr. Hicks is the one</p> <p>13 who brought it to a deposition and went over it.</p> <p>14 MR. SMITH: I don't quarrel. It may</p> <p>15 have come from the FDA. I don't know.</p> <p>16 Q Do you see where it says, "Due to</p> <p>17 separation of John Stuart from government service,</p> <p>18 no methods development investigations were done</p> <p>19 during the first quarter of 1976." Do you see that?</p> <p>20 A I do see that.</p> <p>21 Q If you go to the next page, it states,</p> <p>22 "Due to lack of specialized personnel in certain</p> <p>23 necessary instrumentation, no significant work was</p> <p>24 done on methods developments during the second</p> <p>25 quarter of '76." Do you see that?</p>	<p style="text-align: right;">Page 28</p> <p>1 testing itself on Vermont talcs?</p> <p>2 A Well, I'm aware of FDA doing testing</p> <p>3 multiple times. Several times during the '70s, in</p> <p>4 the '80s, 2009 testing cosmetic talc products,</p> <p>5 including testing of raw materials, and some of</p> <p>6 those would have been from the Vermont mines.</p> <p>7 The exact dates of when they tested</p> <p>8 materials that came from the Vermont mines, I cannot</p> <p>9 speak to that exactly.</p> <p>10 Q So you don't know when the last time the</p> <p>11 FDA personnel was involved in testing talc from the</p> <p>12 Vermont mine?</p> <p>13 MR. SMITH: Objection.</p> <p>14 Q Correct?</p> <p>15 A What I just said, if there's material that</p> <p>16 came out of Vermont and was some in some of those</p> <p>17 cosmetic talcs that were tested several times</p> <p>18 in the '70s, in the '80s and 2009. I don't know</p> <p>19 that there was an exact date that FDA stopped</p> <p>20 testing Vermont talc because I don't know if there's</p> <p>21 Vermont talc in those samples that were tested in</p> <p>22 2009.</p> <p>23 Q As you sit here today, you can't point to</p> <p>24 a single test done by the FDA itself on Vermont talc</p> <p>25 after 1979, correct?</p>
<p style="text-align: right;">Page 27</p> <p>1 A I do.</p> <p>2 Q Do you see where it says, "Because of</p> <p>3 limited resources and in regard to instrumentation</p> <p>4 and trained personnel, the only project plan</p> <p>5 relating to the methods development and sample</p> <p>6 enrichment floatation in order to detect lower</p> <p>7 levels of certainty by DPA." Do you see that?</p> <p>8 A I do.</p> <p>9 Q Now, you are aware, are you not, that the</p> <p>10 FDA has done no testing on Vermont talc since 1979</p> <p>11 itself? You know that, correct?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I don't know the exact dates of testing</p> <p>14 that's been done, but there are multiple</p> <p>15 publications and test reports related to the Vermont</p> <p>16 mines.</p> <p>17 Q I'm asking you whether you know from your</p> <p>18 preparation and review of the documents in your</p> <p>19 possession that the FDA had itself its own</p> <p>20 personnel, has done no testing on any Vermont talc</p> <p>21 since 1979?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A I'm not aware of what dates they did</p> <p>24 Vermont testing.</p> <p>25 Q Do you know if the FDA ever did any</p>	<p style="text-align: right;">Page 29</p> <p>1 MR. SMITH: Objection.</p> <p>2 A So again, there was a survey of cosmetic</p> <p>3 talcs done in 2009. Multiple samples that were</p> <p>4 used. I don't know the origin of all of those</p> <p>5 cosmetic products. They not Johnson and Johnson</p> <p>6 products. It is possible they may have been from of</p> <p>7 the Vermont mine, but I can't speak to that</p> <p>8 directly.</p> <p>9 Q What was my question?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Your question was when was the last date</p> <p>12 did FDA test Vermont talc after 1979. And as I</p> <p>13 said, they tested in the '80s, and again in 2009.</p> <p>14 It is possible some of that material came from the</p> <p>15 Vermont mine.</p> <p>16 Q Ma'am, here is my question, please. As</p> <p>17 you sit here today, you have no evidence in front of</p> <p>18 you to indicate that the FDA itself ever did any</p> <p>19 testing of talc from the Vermont mine after 1979,</p> <p>20 correct?</p> <p>21 A As I --</p> <p>22 MR. SMITH: Objection.</p> <p>23 A As I said, there are multiple surveys that</p> <p>24 were done.</p> <p>25 Q I'm not asking you about multiple surveys.</p>

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<p>1 Please, I'm asking you specifically --</p> <p>2 MR SMITH: You can't talk over the</p> <p>3 witness.</p> <p>4 MR. PLACITELLA: I can talk over the</p> <p>5 witness if she refuses to answer the question.</p> <p>6 MR. SMITH: She is not refusing to</p> <p>7 answer the question.</p> <p>8 MR. PLACITELLA: I'll withdraw the</p> <p>9 question.</p> <p>10 MR. SMITH: Okay. Question</p> <p>11 withdrawn.</p> <p>12 Q Do you believe an honest and forthright</p> <p>13 witness can provide a simple answer to a simple</p> <p>14 question?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A If there's a simple answer, yes. If</p> <p>17 there's not a direct answer to your question, I'll</p> <p>18 give you the related information.</p> <p>19 Q Ma'am, can you show me in any of the books</p> <p>20 that you have in front of you today any testing done</p> <p>21 by the FDA of Vermont source talc after 1979? Show</p> <p>22 it to me.</p> <p>23 A I would be happy to review the results</p> <p>24 from the 1986 survey that was done by FDA and I'll</p> <p>25 be happy to review the 2009 results from the FDA.</p>	<p>1 the provenance of the samples they tested in 1986</p> <p>2 and in 2009.</p> <p>3 Q So you don't know as you sit here today</p> <p>4 that the FDA ever performed any tests on Vermont</p> <p>5 mines after 1979? You don't know that, true?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A What I know is the FDA did testing in 1986</p> <p>8 and in 2009. I don't know the provenance of those</p> <p>9 cosmetic samples because they are not J and J</p> <p>10 samples of cosmetic material. They may have come</p> <p>11 from the Vermont mine. I don't know for sure. They</p> <p>12 are not Johnson and Johnson products.</p> <p>13 Q Let me ask you the question this way. Do</p> <p>14 you have any evidence as you sit here today that the</p> <p>15 FDA ever tested a Johnson and Johnson product after</p> <p>16 1979 that was sourced from the Vermont mine?</p> <p>17 A Well, I'll have to check and see when we</p> <p>18 sourced material from the Vermont mine.</p> <p>19 Q Yes, Ma'am. Go ahead.</p> <p>20 A Maybe we can go to the 1986 test results.</p> <p>21 MR. SMITH: Go to whatever you need</p> <p>22 to go to.</p> <p>23 Q Can you tell me what exhibit you are</p> <p>24 looking at first?</p> <p>25 A This will be the 1986.</p>
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<p>1 As I said, I don't know the source of</p> <p>2 that talc. It is not all Johnson and Johnson talc.</p> <p>3 It may have come from Vermont.</p> <p>4 Q But you don't know?</p> <p>5 A As I said, I don't know specifically if</p> <p>6 those cosmetic products tested in '86 and in 2009</p> <p>7 came from the Vermont mine, but testing was done by</p> <p>8 FDA in those two periods.</p> <p>9 You asked me did the FDA test after</p> <p>10 1979. Maybe. I don't know the provenance of those</p> <p>11 cosmetic samples that came from those other</p> <p>12 companies.</p> <p>13 Q Ma'am, with all due respect, as you sit</p> <p>14 here today, you can't point me to any evidence that</p> <p>15 demonstrates that the FDA tested Vermont talc after</p> <p>16 1979, can you?</p> <p>17 MR. SMITH: Objection.</p> <p>18 Q True?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A As I said, the FDA has tested in '86 and</p> <p>21 again in 2009. I don't know if that cosmetic</p> <p>22 material that came from other companies was from</p> <p>23 Vermont or not, but FDA did do testing.</p> <p>24 So again, I don't know if they tested</p> <p>25 from the Vermont mines or not because I don't know</p>	<p>1 Q The marking on the exhibit for the folder.</p> <p>2 A It says D-237. I don't know what you mean</p> <p>3 by the marking.</p> <p>4 Q The binder is marked with an exhibit</p> <p>5 number, it is not? Look at these and we will mark</p> <p>6 them at a break.</p> <p>7 A This is 1984. November 15, 1984, the</p> <p>8 Food Additives Valuation Branch did an assessment</p> <p>9 and review of talcum powder used for cosmetics,</p> <p>10 which included any relationship to any potential</p> <p>11 asbestos contamination.</p> <p>12 I'm looking to see if there's a list</p> <p>13 here that can tell us what samples -- where the</p> <p>14 samples came from.</p> <p>15 Q Why don't we do this. Take a look during</p> <p>16 the break and we will have everything marked and we</p> <p>17 will get back to that.</p> <p>18 A Okay.</p> <p>19 Q So we are not wasting time. Put a sticker</p> <p>20 on that so you know to go back to it.</p> <p>21 A I know exactly where it is. No sticker</p> <p>22 needed.</p> <p>23 Q Am I correct that even when Johnson and</p> <p>24 Johnson provided information to the FDA, Johnson and</p> <p>25 Johnson controlled what the public could know about</p>

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<p>1 the product safety testing?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A Johnson and Johnson is responsible for</p> <p>4 whatever is on the packaging of the cosmetic talc</p> <p>5 products, if that's what you mean, in compliance</p> <p>6 with the FDA regulations.</p> <p>7 Q No, Ma'am. What I'm asking you is when</p> <p>8 you gave testing information or reports on your talc</p> <p>9 to the FDA, you, Johnson and Johnson, were in</p> <p>10 control of what the FDA could release to the public,</p> <p>11 correct?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A Well, our communications with the FDA,</p> <p>14 that's a privileged proprietary information. So</p> <p>15 that would not be generally publically available.</p> <p>16 I understand people can make a</p> <p>17 request through the Freedom of Information Act to</p> <p>18 get redacted information. I don't know the exact</p> <p>19 process and procedures, but certainly any citizen</p> <p>20 can make that request.</p> <p>21 Q But whether or not the information is</p> <p>22 released by the FDA to the citizen making that</p> <p>23 request is totally within the control of Johnson and</p> <p>24 Johnson, correct?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 A Mr. Johnston, I don't know.</p> <p>2 Q And Mr. Nashed writes to Mr. Johnston,</p> <p>3 "Dr. A. Weisler of the Division of Colors and</p> <p>4 Cosmetics, FDA, informed me today by phone that Dr.</p> <p>5 Zeitz of the Nader Group has asked him to provide</p> <p>6 him with information available to them on the talc</p> <p>7 asbestos question." Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And Dr. Weisler said that Johnson and</p> <p>10 Johnson had submitted reports at various times, most</p> <p>11 of them under a confidentiality statement which are</p> <p>12 not subject to release to the public under the</p> <p>13 Freedom of Information Act. Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Then he goes on to talk about what he told</p> <p>16 the FDA. He said, "I told Dr. Weisler that Johnson</p> <p>17 and Johnson will be happy to discuss release of</p> <p>18 information if it is deemed helpful to the FDA.</p> <p>19 However, since our reports include correspondence</p> <p>20 and opinions from experts, we have submitted such</p> <p>21 reports with the understanding that they are the</p> <p>22 exclusive use of the FDA." Do you see that?</p> <p>23 A Yes.</p> <p>24 Q He goes on to state, does he not, that</p> <p>25 "Unless permission is given, all reports should be</p>
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<p>1 A I don't know that that's true, no.</p> <p>2 Q Do you know that Johnson and Johnson</p> <p>3 actually stopped information on asbestos testing</p> <p>4 that it provided to the FDA from being released to</p> <p>5 the public. You know that, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I don't know what you are referring to.</p> <p>8 I'm happy to look at whatever documents you are</p> <p>9 referring to.</p> <p>10 Q I'm not asking if you are happy to look at</p> <p>11 documents. You are Johnson and Johnson. I'm asking</p> <p>12 you, Johnson and Johnson. You, Johnson and Johnson,</p> <p>13 know that you were controlling exactly what the</p> <p>14 public could see that you gave to the FDA. You know</p> <p>15 that you were doing that, correct?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A That's not correct.</p> <p>18 Q Okay. 465 is a memo from Mr. Nashed to</p> <p>19 D.E. Johnston on June 7, 1973, with subject matter</p> <p>20 talc asbestos, correct?</p> <p>21 A Yes.</p> <p>22 Q Who are these people, Nashed and Johnston?</p> <p>23 A Dr. Nashed is a J and J employee in our</p> <p>24 research and development group at this time.</p> <p>25 Q Who is D.E. Johnston?</p>	<p>1 held in confidence by the FDA." Correct?</p> <p>2 A I see that, yes.</p> <p>3 Q 466 is a November 7, 1973 memo from D.R.</p> <p>4 Pederson. Who is that?</p> <p>5 A I'm not sure.</p> <p>6 Q It is on Johnson and Johnson letterhead?</p> <p>7 A Yes, it is.</p> <p>8 Q What Mr. Pederson writes is, "I want you</p> <p>9 to be aware that certain material previously</p> <p>10 provided to the FDA will be released from our</p> <p>11 confidential disclosure. At that time information</p> <p>12 was given to the FDA in confidence. We have decided</p> <p>13 to release that data pertinent to Shower to Shower</p> <p>14 and Johnson's Medicated Powder, which would dispute</p> <p>15 the information presented in the Lewin report,</p> <p>16 recently released by the FDA. We have decided not</p> <p>17 to release the data either on the Italian mine or on</p> <p>18 Johnson's Baby Powder and Vermont 66 Talc."</p> <p>19 Correct?</p> <p>20 A I see that, yes.</p> <p>21 Q And you understand that one of the missions</p> <p>22 of Johnson and Johnson, when it was dealing with the</p> <p>23 FDA, was to submit rebuttals every time an</p> <p>24 allegation was made that there was asbestos in the</p> <p>25 Johnson and Johnson talc, correct?</p>

<p style="text-align: right;">Page 38</p> <p>1 A Not correct.</p> <p>2 Q And Johnson and Johnson, internally what</p> <p>3 they said they were doing was actually putting out</p> <p>4 fires, right? You have seen that document, correct?</p> <p>5 A You have to show me the document. I don't</p> <p>6 know which document you are referring to.</p> <p>7 Q I'm going to show you what's been marked</p> <p>8 462, and it is entitled Historical Review. Have you</p> <p>9 ever seen this document before?</p> <p>10 A I need a minute to look at it.</p> <p>11 Okay.</p> <p>12 Q I'm looking at the paragraph on the second</p> <p>13 page that talks about when the Food and Drug</p> <p>14 Administration brought talc issue to a head.</p> <p>15 Approximately two years ago, their consultant, Dr.</p> <p>16 Lewin, strongly asserted he had found asbestos in</p> <p>17 Johnson and Johnson powder.</p> <p>18 Johnson and Johnson quickly reacted</p> <p>19 with consultants of their own and after several</p> <p>20 meetings in Washington, Dr. Lewin's original report</p> <p>21 was later amended and he retracted his statements on</p> <p>22 the occurrence of asbestos in Johnson and Johnson</p> <p>23 powder.</p> <p>24 In addition, we have transmitted to</p> <p>25 the FDA formidable rebuttals of any question of the</p>	<p style="text-align: right;">Page 40</p> <p>1 access to FDA officials when safety issues arose</p> <p>2 concerning talc and asbestos, correct?</p> <p>3 A I never heard the term intimate used in</p> <p>4 relation to our relationship with the FDA.</p> <p>5 Q You agree that Johnson and Johnson had a</p> <p>6 far greater access to FDA officials when it came to</p> <p>7 asbestos and talc than an ordinary citizen, correct?</p> <p>8 A That is correct.</p> <p>9 Q And in fact, Johnson and Johnson had a</p> <p>10 greater access than the medical community that was</p> <p>11 in charge of caring for patients hurt by Johnson and</p> <p>12 Johnson when it came to issues of product safety,</p> <p>13 correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Johnson and Johnson did not hurt any</p> <p>16 individuals, so I object to the basis of that</p> <p>17 question.</p> <p>18 Q Let me ask you. Do you agree with me that</p> <p>19 Johnson and Johnson had far greater access to the</p> <p>20 general medical community on issues of asbestos in</p> <p>21 talc, correct?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Greater access to the medical community?</p> <p>24 I don't know what the question is.</p> <p>25 Q Johnson and Johnson had far greater access</p>
<p style="text-align: right;">Page 39</p> <p>1 Occurrence of chrysotile in Johnson and Johnson</p> <p>2 powder. Do you see that?</p> <p>3 A I do.</p> <p>4 Q Do you see on the next page where it talks</p> <p>5 about Johnson and Johnson is putting out fires with</p> <p>6 respect to the specific question of asbestos in</p> <p>7 talc?</p> <p>8 A I see that.</p> <p>9 Q Now, am I correct that Johnson and Johnson</p> <p>10 had intimate access to FDA officials when product</p> <p>11 safety issues arose concerning talc?</p> <p>12 A So the documents you are showing me are</p> <p>13 from the '70s.</p> <p>14 Q That's not my question. I'm not asking</p> <p>15 about these documents. I'm asking you another</p> <p>16 question. So listen to it.</p> <p>17 MR. SMITH: Objection to the</p> <p>18 question. If you are not withdrawing it, she is</p> <p>19 going to finish her answer.</p> <p>20 MR. PLACITELLA: No, I'll withdraw it</p> <p>21 and I'll ask it again.</p> <p>22 Q I'm not asking you about the documents</p> <p>23 we just went through. I'm asking you a different</p> <p>24 question.</p> <p>25 Johnson and Johnson had intimate</p>	<p style="text-align: right;">Page 41</p> <p>1 to the FDA officials in dealing with issues of</p> <p>2 asbestos in talc than the general medical community</p> <p>3 did, correct?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Now I understand your question. Yes, we</p> <p>6 are regulated by the FDA, so of course, we have</p> <p>7 regular and structured interactions with the FDA.</p> <p>8 Q You are aware that FDA officials have left</p> <p>9 government service and went to work for Johnson and</p> <p>10 Johnson, correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes, I'm aware of that.</p> <p>13 Q And you are aware the FDA officials have</p> <p>14 left government service and went to work for the</p> <p>15 industry trade organization that you are a member</p> <p>16 of, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A Yes, I'm aware of that.</p> <p>19 Q And can you tell me as you sit here today</p> <p>20 which government, former government officials you</p> <p>21 are aware of that went to work for Johnson and</p> <p>22 Johnson, former FDA officials?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A The ones the pops into my mind is Dr. Sam</p> <p>25 Maldonado, who leads our Pediatric Center of</p>

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<p>1 Excellence.</p> <p>2 Q Any other?</p> <p>3 A Michelle McMurry is a physician in our</p> <p>4 clinical group in our Device Sector.</p> <p>5 Q Any others?</p> <p>6 A I'm sure there's a long list, but I don't</p> <p>7 know the list.</p> <p>8 Q You are also aware that former executives</p> <p>9 for Johnson and Johnson went to work for the FDA,</p> <p>10 correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes.</p> <p>13 Q Which former executives of Johnson and</p> <p>14 Johnson are you aware of that went to work for the</p> <p>15 FDA?</p> <p>16 A Again, I think Sam Maldonado went to the</p> <p>17 FDA and then came back to Johnson and Johnson and it</p> <p>18 is common in the industry for people who work at the</p> <p>19 FDA for a period of time during their career.</p> <p>20 Q You actually had former executives who</p> <p>21 worked at Johnson and Johnson and then went to work</p> <p>22 at the FDA specifically on the issue of talc safety,</p> <p>23 correct?</p> <p>24 MR. SMITH: Objection.</p> <p>25 A I'm not aware of that, no.</p>	<p>1 leading officials at the FDA involved with the issue</p> <p>2 of asbestos and talc? You didn't know that?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A I was asked to look at the communications</p> <p>5 between Johnson and Johnson and the FDA on asbestos</p> <p>6 testing and talc safety. I didn't look into the</p> <p>7 background of Mr. Eiermann, so no, I was not aware of</p> <p>8 that.</p> <p>9 Q So when you were looking at all these</p> <p>10 documents, you saw documents referencing Mr. Eiermann,</p> <p>11 correct?</p> <p>12 A Yes, I did.</p> <p>13 Q When you looked at all these documents, no</p> <p>14 one in all of Johnson and Johnson told you, hey, that</p> <p>15 guy used to work for us?</p> <p>16 MR. SMITH: Objection.</p> <p>17 Q In fact, was he was one of our executives?</p> <p>18 No one ever told you that?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A No, and I wouldn't expect that because we</p> <p>21 were looking at these documents based on the facts</p> <p>22 and the scientific merit and the context of the</p> <p>23 documents, not where people came from. That's not</p> <p>24 relevant.</p> <p>25 Q So it wasn't relevant that the FDA and</p>
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<p>1 Q You are not aware that you had former</p> <p>2 executives who went to work at the FDA on the issue</p> <p>3 of asbestos in Johnson and Johnson's powder?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A No.</p> <p>6 Q Take a look at 465. Remember 465 is the</p> <p>7 memo that talks about Johnson and Johnson giving the</p> <p>8 FDA permission to release certain information under</p> <p>9 the Freedom of Information Act. Do you remember</p> <p>10 that?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes.</p> <p>13 Q Can you look at the bottom paragraph where</p> <p>14 Mr. Nashed states, "He added that Dr. Eiermann is now</p> <p>15 on deck and will be taking over as Director of the</p> <p>16 Division of Cosmetics and that he, himself is</p> <p>17 phasing out of the area." Do you see that?</p> <p>18 A Yes, I see that.</p> <p>19 Q Did you know Dr. Eiermann was a former</p> <p>20 Johnson and Johnson executive?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A No, I did not.</p> <p>23 Q So you didn't know in preparing for</p> <p>24 today's deposition that a former Johnson and Johnson</p> <p>25 executive actually took control, or was one of the</p>	<p>1 Johnson and Johnson had a revolving door in terms of</p> <p>2 executives and people working on safety issues?</p> <p>3 That wasn't relevant to you?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I disagree with the context of that</p> <p>6 question.</p> <p>7 Q Well, Ma'am, you didn't think it was</p> <p>8 important to know that the person who was one of the</p> <p>9 people in charge of talc safety and asbestos at the</p> <p>10 FDA was your former executive? You didn't think</p> <p>11 that was important?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I don't know of the scope of Mr. Eiermann's</p> <p>14 job at FDA or the scope of his job at Johnson and</p> <p>15 Johnson, and there certainly is no revolving door.</p> <p>16 I really can't speak to that history and what you</p> <p>17 are implying with your question.</p> <p>18 Q Ma'am, you know that when citizens raised</p> <p>19 product safety issues with the FDA concerning talc,</p> <p>20 the first thing the FDA did was pick up the phone</p> <p>21 and call Johnson and Johnson to give them a heads</p> <p>22 up. You knew that, right?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I don't know what you are referring to</p> <p>25 specifically.</p>

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<p>1 Q Do you know as a general matter that any 2 time a safety issue was raised concerning Johnson 3 and Johnson talc, somebody at the FDA picked up the 4 phone and called Johnson and Johnson to give them a 5 heads up. You know that happened, correct? 6 MR. SMITH: Objection. 7 A Well, Johnson and Johnson cosmetics are 8 under the regulatory authority of the FDA, so if 9 somebody brought up a safety issue concerning one of 10 our products, it would be appropriate that they 11 reach out to us directly. 12 I don't know if they called or sent 13 an email or a letter, but absolutely Johnson and 14 Johnson should be notified. 15 Q Right. But they didn't send a letter 16 saying we got this complaint, how do you respond? 17 What they did, your relationship at the FDA was such 18 that if you got a complaint, they picked up the 19 phone and they told you about it first thing, right? 20 That's what happened. 21 MR. SMITH: Objection. 22 Q That's what happened. 23 MR. SMITH: Objection. 24 A I don't know that's true. 25 Q In fact, you kept a file at Johnson and</p>	<p>1 such, but I have memos related to calls between 2 Johnson and Johnson and the FDA. 3 Q So in preparing for today's deposition the 4 lawyers never gave you access to the FDA call file, 5 correct? 6 MR. SMITH: Objection. 7 A You are characterizing a file as a call 8 file. I have not heard that terminology. 9 Q Can you look at 491, please. 491 is a 10 memo on Johnson and Johnson letterhead dated January 11 4, 1984 and the memo is to the FDA call file. Do 12 you see that? 13 A Yes. 14 Q And the re: is talc, correct? 15 A Yes. 16 Q So I'm asking you again, in preparing for 17 today's deposition, the lawyers for Johnson and 18 Johnson, or anybody else at Johnson and Johnson, 19 never gave you access to the complete FDA call file, 20 correct? 21 MR. SMITH: Objection. 22 A So we don't -- you are asking if I had 23 access to something called a call file. All of the 24 documents are no longer in paper files. They are in 25 digital form in a database, and they were searched</p>
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<p>1 Johnson that was dedicated entirely to phone calls 2 that the FDA gave you in order to give you a heads 3 up, correct? 4 MR. SMITH: Objection. 5 A Well, I don't agree with the 6 characterization that there's a heads up phone call 7 file, but of course, it would have been in the 8 natural course of business that we would have kept 9 track of memos related to the content of 10 conversations we had with the FDA. That would have 11 been standard procedure, absolutely. 12 Q There was an FDA call file, correct? 13 A I don't know if that's what they called 14 it, but any communication with the FDA we absolutely 15 should be keeping that as a record. 16 Q Did you review the Johnson and Johnson 17 call file in preparation for today's deposition? 18 A I have numerous memos from Johnson and 19 Johnson related to calls with FDA. I don't know 20 that they specifically came out of this file you are 21 calling the call file, but, yes, I have memos. 22 Q Ma'am, that's not my question. Did you 23 review the Johnson and Johnson call file in 24 preparation for today's deposition? 25 A I have not seen a file characterized as</p>	<p>1 for FDA communications to us, Johnson and Johnson 2 communications to FDA, and they would have included 3 documents related to the phone calls. 4 Q What you are you saying is all the paper 5 was destroyed? 6 MR. SMITH: Objection. 7 A I don't know how our the records are kept. 8 Q You said it is only digital, so what 9 happened to the FDA paper call file? 10 MR. SMITH: Objection. 11 A I don't know what our retention procedures 12 are, so I can't speak to that. 13 Q You understand you didn't have the right 14 or authority to destroy any paper, because you were 15 already sued in talc cases in 1984. You knew that, 16 right? 17 MR. SMITH: Objection. 18 A I don't know about suits in 1984 and I 19 don't know about our retention policy related to 20 talc, so I really can't speak to that. 21 Q Let me ask you the question again. In 22 preparation for today's deposition, you never were 23 provided access, nor did you review, the FDA call 24 file, true? 25 MR. SMITH: Objection.</p>

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<p>1 A Our documents are in digital form. We no 2 longer have physical folders, physical files that 3 you are referring to. So I reviewed documents that 4 were pulled out of our digital files based on a 5 search related to the communications with the FDA 6 and I do have memos and documents related to those 7 communications that I have reviewed.</p> <p>8 There's not a physical form of a file 9 that you are referring to, so I wouldn't have had it 10 in my hands. So your characterization doesn't match 11 up with the way we currently maintain the records.</p> <p>12 Q What was my question? 13 A Your question was about the FDA call file. 14 Q What was my question? 15 A You can read the question again. 16 Q Do you have any idea what my question was? 17 MR. SMITH: Objection. 18 A I have answered your question. 19 Q What was it, if you know you answered the 20 question? 21 MR. SMITH: Objection. 22 A Did I review documents from the FDA call 23 file. 24 Q That wasn't the question. Look at January 25 4, 1984. Did you review this document in</p>	<p>1 I -- I don't recall. 2 Q Is this memo in any of the documents you 3 brought with you today? 4 A No. We brought the substantive documents 5 of the content of exchanges between Johnson and 6 Johnson and the FDA. 7 Q Okay. 8 A This is not a substantive document. 9 Q What this document says is, "In 1984 at 10 9:10 a.m. I received a telephone call from John 11 Weidinger, Deputy Director, Cosmetic Technology 12 Division of FDA. Mr. Weidinger informed me that FDA 13 had received a citizen petition from a Philip 14 Durelay of Stony Brook, New York requesting a warning 15 statement against asbestos contamination in baby 16 powder. John called to request an a copy of an 17 article referenced in the petition." 18 Do you see that? 19 A Yes. 20 Q Am I correct that Johnson and Johnson 21 knew, and was aware, that when need be, it could 22 bypass FDA staff and go directly to the FDA 23 commissioner if it wanted to. 24 MR. SMITH: Objection. 25 A So there's a process to escalate to the</p>
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<p>1 preparation for today's deposition? 2 MR. SMITH: Objection. 3 A I don't recall seeing this specific 4 document. 5 Q Although this came from the FDA call file 6 and related directly to the issue of asbestos in 7 talc, this was not provided to you, fair? 8 MR. SMITH: Objection. 9 A I don't recall seeing this specific memo, 10 but I have many other memos that I reviewed. 11 Q Ma'am, I'm not the asking you about other 12 memos. We will do that later. I'm saying in 13 preparation for today's deposition, you were never 14 provided with this memo from the FDA call file 15 related to asbestos talc testing, correct? 16 A I don't recall seeing this specific memo. 17 Q So the answer to my question is you were 18 never provided it, correct? 19 MR. SMITH: Objection. 20 A So the answer to your question is I don't 21 recall seeing this specific memo. 22 Q So you did get it, you just don't 23 remember? 24 MR. SMITH: Objection. 25 A If I don't remember, how can I tell you if</p>	<p>1 commissioner if there's an issue of sufficient 2 import and merit. 3 Q And when it came to Johnson's Baby Powder, 4 Johnson and Johnson had both the power and the 5 access to bypass FDA staff and go directly to the 6 FDA commissioner, if it wanted to, correct? 7 MR. SMITH: Objection. 8 A As I said, for topics of significant 9 import, absolutely we could escalate to the 10 commissioner as needed. 11 Q No citizen or doctor had that kind of 12 access, correct? 13 MR. SMITH: Objection. 14 A I believe the citizens' petition process 15 is the mechanism by which citizens can approach the 16 FDA when they have certain concerns apropos the memo 17 you showed me. 18 Q So you think an average citizen can just 19 bypass the FDA staff and go right to the 20 commissioner when it has issue? That's what you 21 believe? 22 MR. SMITH: Objection. 23 Q Just like Johnson and Johnson can? 24 MR. SMITH: Objection. 25 A We don't bypass. We escalate, meaning if</p>

<p style="text-align: right;">Page 54</p> <p>1 there's an issue that's been discussed with the FDA 2 staff members as appropriate to preview a topic and 3 there's some issue that arises that needs a higher 4 level of interaction, those issues can be escalated, 5 but we do not bypass the communication process. 6 MR. SMITH: While there is no 7 question pending, can we have a bathroom break? 8 THE VIDEOGRAPHER: The time is 9 approximately 11:03 a.m and we are going off the 10 record. 11 (Recess taken) 12 (Notebooks are marked P-3, 4 and 5.) 13 14 THE VIDEOGRAPHER: We are back on the 15 record. The time is approximately 11:14 a.m. 16 17 BY MR. PLACITELLA: 18 19 Q Dr. Nicholson, before we broke you talked 20 about the ability to escalate an issue to the 21 commissioner. What was the process for doing that? 22 A I don't know the exact process. 23 Q What kind of issues got escalated to the 24 commissioner? 25 MR. SMITH: Objection.</p>	<p style="text-align: right;">Page 56</p> <p>1 A I don't know. 2 Q Now, when Johnson and Johnson feels like 3 it is suffering from adverse public relations 4 concerning the safety of its products, is that the 5 type of thing they escalate to the commissioner of 6 the FDA? 7 MR. SMITH: Objection. 8 A No. Public relations has nothing to do 9 with FDA interactions and what things would 10 escalate. 11 Q Well, you did understand and consider 12 escalating the issues related to the safety of baby 13 powder and asbestos to the commissioner, correct? 14 MR. SMITH: Objection. 15 A Not the safety of asbestos and baby 16 powder. The issue was testing of asbestos in baby 17 powder, and the fact that there was incorrect 18 testing results and people were making significant 19 decisions based on incorrect testing methods. 20 Q And it was Johnson and Johnson's position 21 that they needed to go directly to the commissioner 22 and voice their position, correct? 23 MR. SMITH: Objection. 24 A No. That's not correct. 25 Q I'm not correct? What is correct?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q By Johnson and Johnson. 2 A I think escalations were extremely rare. 3 If there's a discussion about a specific topic at a 4 certainly level of management, whether it be with 5 the director of the cometic division, then that 6 could be escalated to the commissioner. 7 Q Does the ordinary citizen have the ability 8 to do that? 9 A An ordinary citizen would use the citizen 10 petition process to interact with the FDA. 11 Q So the ordinary citizen has no ability to 12 get directly to the FDA commissioner like Johnson 13 and Johnson does, correct? 14 A I don't know if they can or cannot reach 15 the commissioner. 16 Q What about medical doctors who are 17 concerned about the safety and health of their 18 patients? Do they have direct access to the 19 commissioner? 20 MR. SMITH: Objection. 21 A I don't know. 22 Q What about members of Congress, can they 23 just call up the commissioner and demand access to 24 the commissioner? 25 MR. SMITH: Objection.</p>	<p style="text-align: right;">Page 57</p> <p>1 MR. SMITH: Objection. 2 A Johnson and Johnson deals directly with 3 the individuals responsible for the oversight of 4 cosmetics. If there's some issue that needs to be 5 escalated based on various considerations of the 6 importance and impact, that could be escalated to 7 the commissioner. 8 Q Well, Johnson and Johnson took the 9 position that it had access to the commissioner on 10 the issue of whether asbestos was in baby powder, 11 correct? 12 A Incorrect. 13 Q 476 is an addendum to memorandum from 14 March 23, 1972. Have you seen this before? 15 A I need one minute to look at it. 16 Q Sure. 17 A I have seen communications related to this 18 topic. I don't know if I've seen this exact 19 addendum. Without seeing the rest of the documents, 20 it is hard to tell. 21 Q It is not part of the information you 22 reviewed in preparation for today's deposition? 23 MR. SMITH: Objection. 24 A I didn't say that. I reviewed -- if I 25 reviewed it, I reviewed the whole letter. You only</p>

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<p>1 gave me a page.</p> <p>2 Q Do you have the whole letter, because I</p> <p>3 don't have it?</p> <p>4 A I may. If you would like, I'll take time</p> <p>5 to look through.</p> <p>6 Q Let's make a note of things we want to</p> <p>7 look at during the break.</p> <p>8 Do you see here it talks about a call</p> <p>9 with the Deputy Director, Bureau of Foods? Do you</p> <p>10 see that?</p> <p>11 A Yes.</p> <p>12 Q About Johnson's Baby Powder.</p> <p>13 A I see that.</p> <p>14 Q Do you see it says, "I reviewed further</p> <p>15 with Mr. Bernard the advisability of Johnson and</p> <p>16 Johnson going to the commissioner to inform him of</p> <p>17 our data regarding our baby powder being free of</p> <p>18 asbestos so that he will be prepared to allay the</p> <p>19 panic of the mothers which may result from the</p> <p>20 consumer initiated publicity."</p> <p>21 A Yes.</p> <p>22 Q Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Did that ever happen?</p> <p>25 A That they discussed with the commissioner.</p>	<p>1 Q When the FDA made a decision how they were</p> <p>2 going to respond to citizens raising questions about</p> <p>3 the safety of baby powder, they actually went to</p> <p>4 Johnson and Johnson and said, can you give us the</p> <p>5 research to support our decision, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 Q Even after they made the decision,</p> <p>8 correct?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A I'm sorry, I'm confused by your question.</p> <p>11 Q When the FDA was responding to concerns</p> <p>12 that were raised by citizens about the safety of</p> <p>13 baby powder, it actually went to Johnson and Johnson</p> <p>14 and said, this is what we decided, but we need you to</p> <p>15 give us the backup for our analysis. That's what</p> <p>16 happened, right?</p> <p>17 MR. SMITH: Objection.</p> <p>18 Q That's how intimate the connection was</p> <p>19 between the two of you.</p> <p>20 MR. SMITH: Objection.</p> <p>21 Q Correct?</p> <p>22 A No. I disagree with your</p> <p>23 characterization.</p> <p>24 Q 497 is correspondence from Craig Bernard</p> <p>25 dated November 3, 2008, subject, meeting with J and</p>
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<p>1 I believe there was a discussion with the</p> <p>2 commissioner.</p> <p>3 Q Now when the FDA is responding to citizens</p> <p>4 concerns about the safety of baby powder, it, in</p> <p>5 fact, relied upon Johnson and Johnson for research</p> <p>6 and support in order to respond to those concerns.</p> <p>7 Is that true?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A In 1972, there was a lot of work being</p> <p>10 done around asbestos testing and incorrect test</p> <p>11 results coming out. Johnson and Johnson's Baby</p> <p>12 Powder is free of asbestos. So there were some</p> <p>13 concerns about incorrect information being</p> <p>14 attributable to our products.</p> <p>15 Q That wasn't my question. My question was</p> <p>16 when the FDA is responding to citizens concerns</p> <p>17 about the safety of Johnson's Baby Powder, it</p> <p>18 actually relied upon Johnson and Johnson to help</p> <p>19 write and respond to the citizens concerns, correct?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A I'm not sure I agree with that</p> <p>22 characterization, but I'll say that Johnson and</p> <p>23 Johnson was very involved in the technologic</p> <p>24 methodological development of asbestos testing because</p> <p>25 we had significant expertise in this area.</p>	<p>1 J. Do you see that?</p> <p>2 A Yes, I do.</p> <p>3 Q It states, "Hi, Mark. You recall a couple</p> <p>4 of months ago we met with Bill Casalaris' office</p> <p>5 and spoke about the citizens petition with the FDA</p> <p>6 that is requesting to have warning labels placed on</p> <p>7 products containment. Here is an update on that</p> <p>8 activity. Kathy Willie," do you know who Kathy</p> <p>9 Willie is?</p> <p>10 A She's a former Johnson and Johnson</p> <p>11 employee.</p> <p>12 Q What was her job?</p> <p>13 A I don't recall her exact title.</p> <p>14 A "Kathy Willie at Johnson and Johnson</p> <p>15 informed me that at a recent science meeting in</p> <p>16 Washington, D.C. she had a side conversation with a</p> <p>17 key figure from the FDA cosmetic group that is</p> <p>18 responsible for responding to the citizens</p> <p>19 petition."</p> <p>20 Do you know anything about a side</p> <p>21 conversation?</p> <p>22 A I'm reading this here.</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I'm looking at this here. This is an</p> <p>25 Imerys document.</p>

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<p>1 Q Do you know anything about the side 2 conversation that you, Johnson and Johnson, had with 3 the FDA official in 2008 referenced here? 4 MR. SMITH: Objection. 5 A This is the only reference I've seen to 6 that conversation. I'll point out, again, this is 7 an Imerys document. 8 Q But it is their business record about a 9 meeting it had with you, Johnson and Johnson. 10 Right? 11 MR. SMITH: Objection. 12 A It is an e-mail from one person to another 13 with an Imerys referring to some conversation that 14 was had, that's correct. 15 Q With Johnson and Johnson? 16 A Correct. 17 Q He indicated the "FDA would rule against 18 the petition and would not require a warning label 19 on cosmetic products, but the FDA is looking for 20 scientific support from industry that will help 21 justify their position." Do you know anything about 22 that? 23 A I don't know about this side conversation, 24 but I'm reading down further and I know what they 25 are referring to with regard to development of a review</p>	<p>1 done and that was a review of the scientific 2 literature related to a specific safety concern, 3 which was prepared and available to the FDA. 4 Q Ma'am, what I'm asking you is do you know 5 anything about these side conversations that Johnson 6 and Johnson executives were having with people at 7 the FDA asking for support for denying citizen 8 petitions. That's all I'm asking. 9 Do you know anything, since you are 10 here on behalf of Johnson and Johnson and the 11 communications it had with the FDA. Do you know 12 anything about those side conversations? 13 MR. SMITH: Objection. This witness 14 is here about communications. 15 MR. PLACITELLA: Please don't do 16 this. 17 MR. SMITH: Regarding testing for 18 asbestos. That's why she is here. 19 Q Do you know anything about the side 20 conversation, Ma'am? 21 A I only know what's written here in this 22 Imerys document. I have not seen this before and it 23 is not related to asbestos testing. 24 Q It says on the bottom, I'll highlight it 25 for you.</p>
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<p>1 article related to talc safety. 2 Q But you don't know anything about the side 3 conversation with the FDA asking Johnson and Johnson 4 for support in order to deny the citizen's petition. 5 Do you know about that side conversation? 6 MR. SMITH: Objection. 7 A I'm reading this along with you and 8 I see the FDA had already made their decision about 9 the petition and they were looking for some 10 scientific support, and supposedly that was part of 11 this conversation that you are pointing out in this 12 memo that is an Imerys memo. 13 Q That's exactly my point. So even after 14 the FDA had made its decision, it went to Johnson 15 and Johnson and said, can you give us some support 16 for we are about to say. That's what happened, 17 according to this memo. 18 MR. SMITH: Objection. 19 Q Right? 20 A I believe in your question you are 21 implying they had scientific support, but they were 22 going to rule against it. I think that's an 23 incorrect characterization. 24 I'm well aware of the Muscat and 25 Huncharek epidemiologic review of talc safety that was</p>	<p>1 "We also know the FDA is looking to 2 include in their comments that talc does not contain 3 asbestos, and thus talc use would not cause a 4 concern from this risk perspective. We know this 5 because FDA asked Personal Care Products Council for 6 their updated specifications for talc, which the 7 council in turn asked J and J and RTM for assistance 8 with." Do you see that? 9 A Yes. 10 Q So this document does talk about asbestos 11 testing and information available from 12 Johnson and Johnson, correct? 13 MR. SMITH: Objection. 14 A That's not correct. It says that the talc 15 does and they are making reference to the industry 16 specification they are getting, not from Johnson and 17 Johnson, but the Personal Care and Product Council. 18 Q Who went to Johnson and Johnson and asked 19 for help, correct? 20 MR. SMITH: Objection. 21 A I can't follow who went to what for whom. 22 There are probably four different people mentioned 23 in that sentence. 24 A Says counsel in turn asked Johnson and 25 Johnson for assistance. Is it that hard to read?</p>

<p style="text-align: right;">Page 66</p> <p>1 MR. SMITH: Objection.</p> <p>2 A I hear your question. They are referring</p> <p>3 to the J41 specification for cosmetic talc that you</p> <p>4 get off of internet, so I don't see they would need</p> <p>5 J and J's assistance to Google it and print it out.</p> <p>6 Q Ma'am, did I ask you anything about Google</p> <p>7 or J41?</p> <p>8 A You did.</p> <p>9 Q I didn't.</p> <p>10 A You asked about this updated specification</p> <p>11 for talc.</p> <p>12 Q Ma'am, all I asked you was, does this memo,</p> <p>13 in fact, reference asbestos testing and the issue of</p> <p>14 asbestos in talc. That was my question.</p> <p>15 A This memo specifically said talc, not</p> <p>16 containing asbestos in the current product</p> <p>17 specifications, which would go to the fact that this</p> <p>18 is talc not containing asbestos.</p> <p>19 I'm well aware of this time period</p> <p>20 and the topic at hand, and it is not about asbestos</p> <p>21 testing.</p> <p>22 Q Let me read it for the record and then</p> <p>23 I'll move on. "We also know the FDA is looking</p> <p>24 to include in their comments that talc does not</p> <p>25 contain asbestos, and thus talc use would not cause</p>	<p style="text-align: right;">Page 68</p> <p>1 A That is correct. In the late '60s and</p> <p>2 early '70s, people were talking about the health</p> <p>3 effects of tremolite and those issues were dealt</p> <p>4 with with preclinical animal testing.</p> <p>5 Q I didn't ask you about animal testing.</p> <p>6 I'm asking you a very specific question. Am I</p> <p>7 correct that as far back as 1969, Johnson and</p> <p>8 Johnson's medical director had concerns about the</p> <p>9 health effects related to tremolite, that's my</p> <p>10 question.</p> <p>11 MR. SMITH: Objection.</p> <p>12 Q Not what you did in response. I'll ask</p> <p>13 that as a separate question. Do you understand</p> <p>14 that?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I understand your question. The way you</p> <p>17 are phrasing it is misleading, and it implies that</p> <p>18 for many years starting in 1969, people were</p> <p>19 concerned about tremolite, and that's incorrect.</p> <p>20 It was a very small period of time people were</p> <p>21 concerned and that scientific question was dealt</p> <p>22 with in the early '70s with preclinical animal</p> <p>23 testing.</p> <p>24 Q And it was totally resolved from Johnson</p> <p>25 and Johnson's perspective in the early '70s, the</p>
<p style="text-align: right;">Page 67</p> <p>1 a concern from this risk perspective." That's what</p> <p>2 it says, correct?</p> <p>3 A That's what it says, yes.</p> <p>4 Q I want to talk a minute about potential</p> <p>5 hazards related to talc that were known and</p> <p>6 discussed inside Johnson and Johnson relevant to</p> <p>7 whether talc was misbranded under FDA regulations.</p> <p>8 Okay? Are you with me?</p> <p>9 A Yes.</p> <p>10 Q Am I correct, and can we agree, that</p> <p>11 Johnson and Johnson was concerned about the medical</p> <p>12 effect of tremolite for decades prior to the 2008</p> <p>13 petitions?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Not for the decades prior to 2008.</p> <p>16 Q Can we agree that as far back as 1969 the</p> <p>17 Johnson and Johnson medical director expressed</p> <p>18 concern about the medical effects of tremolite?</p> <p>19 MR. SMITH:</p> <p>20 A In the late '60s and early '70s there were</p> <p>21 questions about tremolite and that was dealt with</p> <p>22 with some preclinical animal studies.</p> <p>23 Q Am I correct as far back as 1969 the</p> <p>24 medical director of Johnson and Johnson was</p> <p>25 concerned about the health effects of tremolite?</p>	<p style="text-align: right;">Page 69</p> <p>1 potential health effects from tremolite. Is that</p> <p>2 what you are saying?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A Yes.</p> <p>5 Q Can we agree that Johnson and Johnson's</p> <p>6 Baby Powder products contained tremolite and</p> <p>7 actinolite that were classified as fiber by federal</p> <p>8 regulations?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A That is a compound question that you are</p> <p>11 asking. Tremolite and actinolite are not asbestos.</p> <p>12 Q Ma'am, that's not my question. My</p> <p>13 question is can we agree that talc baby products</p> <p>14 that contained tremolite and actinolite were</p> <p>15 classifiable as fiber under federal regulations?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A You have to show me the regulations you</p> <p>18 are referring to.</p> <p>19 Q J44 is an April 26, 1973 memo to Mr.</p> <p>20 Johnston on Johnson and Johnson letterhead,</p> <p>21 correct?</p> <p>22 A Yes.</p> <p>23 Q This was after the time you say Johnson</p> <p>24 and Johnson hadn't resolved the issue of whether</p> <p>25 there was a danger related to tremolite, correct?</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A That's correct, in preclinical animal</p> <p>3 testing.</p> <p>4 Q You are familiar with this document?</p> <p>5 A I've seen this document, yes.</p> <p>6 Q In this document it talks about a visit to</p> <p>7 the mine by Mr. Ashton and Mr. Miller and Mr.</p> <p>8 Zeitz, correct?</p> <p>9 A Yes.</p> <p>10 Q And it says, "It is our joint conclusion</p> <p>11 that we should not rely on the clean mine approach</p> <p>12 as a protective device for baby powder in the</p> <p>13 current asbestos or asbestiform controversy. We</p> <p>14 believe this mine to be very clean, however, we are</p> <p>15 also confident that fiber forming or fiber type</p> <p>16 materials could be found. Usefulness of the clean</p> <p>17 mine approach for asbestos only is over." Do you</p> <p>18 see that?</p> <p>19 A Yes.</p> <p>20 Q When you go to the second page, the reason</p> <p>21 I'm asking you this because it is about the FDA. It</p> <p>22 says, "if the FDA Food Division, which is moving</p> <p>23 more rapidly than the cosmetic division, publishes a</p> <p>24 standard, it will be probably to ban an asbestiform</p> <p>25 or fibrous material in talc. That could eliminate</p>	<p>1 non-asbestiform tremolite, as of at least 1974, could</p> <p>2 be ground up and satisfy the definition of</p> <p>3 asbestiform tremolite, correct?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I don't recall that specific statement,</p> <p>6 but I'll restate anything before 1976 with the J41</p> <p>7 standard is likely to be confused and incorrect with</p> <p>8 regard to the characterization of asbestos.</p> <p>9 Q We are going to get to that, I promise</p> <p>10 you.</p> <p>11 364 is a memo from the FDA dated May</p> <p>12 14, 1974. You have seen this, correct?</p> <p>13 A I need one minute to look at it, please.</p> <p>14 Go ahead.</p> <p>15 Q In this memo, the FDA states, "Tremolite</p> <p>16 is the commonest asbestos mineral found as a</p> <p>17 contaminant of talc. It occurs in asbestiform and</p> <p>18 non-asbestiform varieties. This sample is a chunky</p> <p>19 tremolite, not the asbestiform variety. But when it</p> <p>20 is ground, it produces some thin, straight particles</p> <p>21 which conform to the definition of fibers in the</p> <p>22 method which our distinguishable produced by</p> <p>23 asbestiform tremolite on grinding."</p> <p>24 That is something that Johnson and</p> <p>25 Johnson understood as of this time, correct?</p>
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<p>1 the current uses of talc in packaging materials.</p> <p>2 These talc contained wildly varying amounts of</p> <p>3 tremolite or fibrous talc. Our Baby Powder contains</p> <p>4 talc fragments classifiable as fiber. Occasionally</p> <p>5 subtrace quantities of tremolite or actinolite are</p> <p>6 identifiable on the microscope and these might be</p> <p>7 classified as asbestos fibers." Did I read that</p> <p>8 correctly?</p> <p>9 A You did.</p> <p>10 Q Now, you understand that it was, and can</p> <p>11 we agree that the FDA's position was that "non</p> <p>12 asbestiform tremolite could be ground up so that it</p> <p>13 conformed to the definition of fiber requiring</p> <p>14 regulation and that it would be as indistinguishable</p> <p>15 from asbestos tremolite." You, Johnson and Johnson,</p> <p>16 knew that, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A You are showing me documents from the</p> <p>19 early '70s, so I need to know what documents you are</p> <p>20 referring to because whatever was done before 1976</p> <p>21 is during methods developments, so any definitive</p> <p>22 statements during that time around the</p> <p>23 characterization of asbestos are probably incorrect.</p> <p>24 Q Ma'am, that's not my question, please. My</p> <p>25 question is, it was the position of the FDA that</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A That is correct. This in the context of</p> <p>3 developing methods. They are not saying tremolite</p> <p>4 is asbestos. They are trying to figure out what is</p> <p>5 the right method to use to distinguish between other</p> <p>6 particles and the type of asbestos that could be</p> <p>7 harmful.</p> <p>8 Q Ma'am, I know you have a story to tell and</p> <p>9 you can do it when your lawyer asks you questions.</p> <p>10 But I would ask you, please, to just answer my</p> <p>11 question.</p> <p>12 My question was not -- didn't ask for</p> <p>13 a long explanation. You understand that, right?</p> <p>14 MR. SMITH: Let me state for the</p> <p>15 record, Dr. Nicholson, just ignore those insulting</p> <p>16 comments. Just ignore them. Okay. You are here.</p> <p>17 Listen to the question, answer it.</p> <p>18 The gratuitous comments we can't</p> <p>19 stop. I'm told this is how he behaves at a</p> <p>20 deposition, but just ignore it, okay?</p> <p>21 A Yes. Could you restate your question,</p> <p>22 please?</p> <p>23 Q Sure. In this memo, the FDA is stating a</p> <p>24 position concerning tremolite. That's all I'm</p> <p>25 asking you, correct?</p>

<p style="text-align: right;">Page 74</p> <p>1 A That's incorrect. In this memo the FDA is 2 talking about methods to distinguish asbestos, real 3 asbestos using different microscopic techniques. 4 This is not a declaration of a position, it is a 5 discussion of methods. 6 Q Can you show me, Ma'am, in any of the 7 materials you brought with you today where the FDA 8 changed its position concerning non-asbestiform 9 tremolite being -- and if you can tag that, we will 10 do that after lunch can you do that? 11 MR. SMITH: Objection to the form. 12 Q Let me ask you this question. Am I 13 correct, and can we agree that five to eight percent 14 of the Johnson and Johnson talc, talc sold by 15 Johnson and Johnson, contained particles that are 16 capable of damaging the lungs of human beings? 17 MR. SMITH: Objection. 18 A No. 19 Q 467 is an August 13, 1971 memo on Johnson 20 and Johnson letterhead, the subject being talc. I'm 21 going to refer you to Section G. It states, "It is 22 generally accepted that the lung damaging particles 23 of minerals are below ten microns. Roughly we have 24 about five to eight percent of such in our talc." 25 Did I read that correctly?</p>	<p style="text-align: right;">Page 76</p> <p>1 A Let me review the document. There are 2 multiple points in here, not necessarily related. 3 Okay. Go ahead. Your question, 4 please. Please ask the question again. 5 Q This particular document talks about talc 6 that was being mined and sold by Johnson and 7 Johnson, correct? 8 A That is correct, from Windsor Minerals, 9 which contain industrial talc as well as cosmetic 10 talc, and it is very difficult to see what they are 11 referring to in different points. There's a 12 mixture. 13 Q You understand that both the industrial 14 talc and the cosmetic talc sold by Johnson and 15 Johnson came out of the exact same Hammondsville 16 mine. You know that, correct? 17 A That is not correct. There were different 18 mines, mine shafts and geographic locations for 19 cosmetic versus industrial talc. 20 Q That wasn't my question. Do you 21 understand, Ma'am, that the cosmetic and industrial 22 talc sold by Johnson and Johnson came out of the 23 Hammondsville mine, correct? 24 MR. SMITH: Objection. 25 Q You know that?</p>
<p style="text-align: right;">Page 75</p> <p>1 A You did read that correctly, but we don't 2 know this refers to cosmetic talc. We have to go 3 back and review the beginning of the document. 4 Absolutely incorrect for our cosmetic talc and has 5 always been true. 6 Q So it has been true for your industrial 7 talc, but not your cosmetic talc. Is that what you 8 are saying? 9 A What I'm saying is I'll need to go back 10 and look because cosmetic talc does not contain 11 particles. 12 Q Okay. Go back and look. Let me help you. 13 Look at Section C. It says the, Bureau of Mines 14 expert who testified at the behest of the FDA 15 commented on the poor grade talc in our Windsor 16 Mine, but mentioned the ore next to the outlying 17 rock contained asbestos. It is imperative that 18 careful selection of the ore be maintained at the 19 mines. It is always possible that the FDA may 20 inspect the mines and our records." Do you see 21 that? 22 A Yes. 23 Q What they are talking about, and when you 24 look at B, they are talking about the Shower to 25 Shower and your medicated product, correct?</p>	<p style="text-align: right;">Page 77</p> <p>1 A That wasn't your question before. You 2 said the exact same mine. They come from different 3 mine shafts, different quality of talc, just to be 4 clear. 5 Q Can we agree, Ma'am, that the cosmetic 6 talc and industrial talc that was sold by Johnson 7 and Johnson came out of the Hammondsville mine owned 8 by Johnson and Johnson? 9 MR. SMITH: Objection. 10 A I don't know the names of all the mines. 11 I don't believe Hammondsville was the only source of 12 talc, so I can't answer that specifically. But I 13 know that cosmetic talc did not come from the 14 same geologic formations. 15 Q How do you know that? 16 A I've read many documents, spoken to many 17 experts in the field including John Hopkins and 18 other consultants that we have. They are expert 19 geologists. 20 Q So let's just be clear where we are. Are 21 you saying that the cosmetic talc and the industrial 22 talc sold by Johnson and Johnson did not come from 23 the Hammondsville mine? 24 MR. SMITH: Objection. 25 A I didn't say that.</p>

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<p>1 Q So my question was, according to Johnson 2 and Johnson, it is generally accepted that lung 3 damaging particles of minerals are below ten microns 4 and that according to Johnson and Johnson, you had 5 about five to eight percent of such minerals in your 6 talc as of 1971, correct?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A I'm reading the statement here as you are. 9 That's what it says.</p> <p>10 Q Now, am I correct that the talc in Johnson 11 and Johnson products is capable of reaching, when 12 inhaled, is capable of reaching deep into the human 13 organs?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A I'm not an inhalation toxicology expert.</p> <p>16 Q Do you agree with me that inhaled talc 17 could reach deep into the lungs?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I'm not an inhalation toxicology expert.</p> <p>20 Q You don't know that? You, Johnson and 21 Johnson, don't know that?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A I'm not -- I personally am not an 24 inhalation toxicology expert, so I can't comment on 25 that.</p>	<p>1 lawyer, I'm asking you to answer my question. 2 As you sit here today you no evidence 3 that Johnson and Johnson ever revealed to the FDA 4 that it was of the opinion that inhaled talc could 5 reach deep into the lungs, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I have not reviewed the inhalation 8 communications between the FDA and Johnson and 9 Johnson.</p> <p>10 Q Now, am I correct, or can we agree that 11 Johnson and Johnson internally acknowledged that 12 very low levels of chrysotile asbestos found as a 13 contaminant in talc pose a severe health hazard?</p> <p>14 MR. SMITH: Objection. Can you read 15 that question back.</p> <p>16 (The above question is read.)</p> <p>17 MR. SMITH: Note my objection.</p> <p>18 A I didn't understand the question.</p> <p>19 Q Can we agree internally at Johnson and 20 Johnson that you acknowledged that very low levels 21 of exposure to chrysotile asbestos found as a 22 contaminant in talc, pose a severe health hazard?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A No.</p> <p>25 Q 69 is the Johnson and Johnson Baby Powder</p>
Page 79	Page 81
<p>1 Q Do you know whether Johnson and Johnson 2 ever related to the FDA that inhaling its talc could 3 reach deep into the lungs?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Since I'm not an expert in that area, I 6 would not recall specifics of that information.</p> <p>7 Q So as you sit here today, you, Johnson and 8 Johnson, don't know whether you ever told the FDA 9 that inhaled talc could reach deep into the lungs?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A I'm not an inhalation toxicology expert. 12 I can't comment on that.</p> <p>13 Q I'm not asking whether you are an expert. 14 I'm asking about what information Johnson and 15 Johnson had that was related to the FDA.</p> <p>16 As you sit here today, you, Johnson 17 and Johnson, have no evidence that you ever told the 18 FDA that inhaled talc could reach deep into the 19 lungs, correct?</p> <p>20 MR. SMITH: objection.</p> <p>21 A My scope for today was information about 22 asbestos testing communications between the FDA and 23 Johnson and Johnson. Your question is outside of 24 the scope.</p> <p>25 Q With all due respect, you are not a</p>	<p>1 fact book, July 1974. I'm going to refer you -- who 2 is Vernon Zeitz? Do you know?</p> <p>3 A I don't know Vernon Zeitz.</p> <p>4 Q And I'm going to refer you to page 5, 5 under summary and remarks. It states, "The use of 6 citric acid in the depression of chrysotile asbestos 7 and other mineral species has been developed at 8 Windsor Minerals in response to the potential need 9 for means to exclude extremely local levels of these 10 contaminants from the finished product of the 11 benefaction process. The use of these systems is 12 strongly urged by the writer to provide the 13 protection against what are currently considered to 14 be materials presenting a severe health hazard and 15 are potentially present in all talc ores in use at 16 this time." Did I read that correctly?</p> <p>17 A You did.</p> <p>18 Q Did you ever see this before?</p> <p>19 A I haven't. This document is called a 20 floatation method and so it would take some review 21 and discussion with an expert to really understand 22 what this is about, what it is referring to.</p> <p>23 Q So you never saw this document at any time 24 in preparation for testimony you have given 25 anywhere?</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A I don't recall seeing it before. I may</p> <p>3 have, but I certainly did not review it in detail</p> <p>4 for today.</p> <p>5 Q Can we agree that Johnson and Johnson</p> <p>6 those and acknowledges that talc containing</p> <p>7 asbestiform fibers is a known human carcinogen?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Can you read that again? There was a bit</p> <p>10 confusing to me.</p> <p>11 Q Yes. Can we agree that you, Johnson and</p> <p>12 Johnson, acknowledge that talc containing</p> <p>13 asbestiform fibers is a known human carcinogen?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A We know that asbestos is a carcinogen, if</p> <p>16 that's your question.</p> <p>17 Q My question is, talc containing</p> <p>18 asbestiform fibers is a known human carcinogen.</p> <p>19 That's something you know at Johnson and Johnson,</p> <p>20 correct?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A That is correct, that asbestos is a</p> <p>23 carcinogen. If it were any of our products, it</p> <p>24 would still be a carcinogen.</p> <p>25 Q Now, Johnson and Johnson, can we agree</p>	<p>1 Can you clarify?</p> <p>2 Q Sure. Let me ask you. Maybe that was a</p> <p>3 bad question.</p> <p>4 Can we agree that were reports in the</p> <p>5 scientific literature indicating that talc</p> <p>6 contaminated with asbestos is a cause of</p> <p>7 mesothelioma in women?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A I'm not aware of that literature.</p> <p>10 Q Am I correct that, and can we agree, that</p> <p>11 Johnson and Johnson internally has acknowledged that</p> <p>12 because tremolite and anthophyllite are known</p> <p>13 contaminants of talc, data suggests that rare cases</p> <p>14 of mesothelioma among women with no other</p> <p>15 identifiable exposure might be related to exposure</p> <p>16 to cosmetic talc?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A No.</p> <p>19 Q 216 is a memo from 1977 entitled</p> <p>20 Mesothelioma Talc Medical Research. Do you see</p> <p>21 that?</p> <p>22 A Yes.</p> <p>23 Q With Johnson and Johnson Bates number on</p> <p>24 it. Do you see that?</p> <p>25 A Yes.</p>
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<p>1 that Johnson and Johnson knows and acknowledges</p> <p>2 people can development the disease mesothelioma from</p> <p>3 non occupational exposure to asbestos?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Yes.</p> <p>6 Q Can we agree that studies that Johnson and</p> <p>7 Johnson were aware of demonstrate that both talc and</p> <p>8 asbestos have been found in women who are non</p> <p>9 occupationally exposed to asbestos?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Yes.</p> <p>12 Q Can we agree that tremolite and</p> <p>13 anthophyllite are known contaminants of talc?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A They can be. They are not asbestos.</p> <p>16 Q Can we agree that talc, contaminated talc,</p> <p>17 has been implicated as a cause of mesothelioma in</p> <p>18 women?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Contaminated talc. You have to be more</p> <p>21 specific.</p> <p>22 Q Talc contaminated with asbestos has been</p> <p>23 implicated as a cause of mesothelioma in women.</p> <p>24 MR. SMITH: Objection.</p> <p>25 A What do you mean by implicated, please?</p>	<p>1 Q If we go to the section of the memo on</p> <p>2 talc, it states, "However, in several mesothelioma</p> <p>3 patients studied both talc fibers and tremolite were</p> <p>4 detected. In fact, the majority of asbestos bodies</p> <p>5 isolated from the lungs of women in the general</p> <p>6 population have tremolite or anthophyllite, and</p> <p>7 because tremolite and anthophyllite are known</p> <p>8 contaminants of talc, this data suggests that rare</p> <p>9 cases of mesothelioma among women with no other</p> <p>10 identifiable exposure might be related to exposure</p> <p>11 to cosmetic talc." Did I read that correctly?</p> <p>12 A You read that correctly, but I disagree</p> <p>13 with that conclusion.</p> <p>14 Q I wasn't asking you what you agree with.</p> <p>15 I was asking you whether this was information in the</p> <p>16 possession of Johnson and Johnson.</p> <p>17 A This is information in the possession of</p> <p>18 Johnson and Johnson, but there are rare cases with</p> <p>19 no identifiable, might be related. It is not</p> <p>20 scientific data, it is a hypothesis.</p> <p>21 Q Ma'am, I'm just asking whether the</p> <p>22 information contained in this Johnson and Johnson</p> <p>23 document was information known to Johnson and</p> <p>24 Johnson, at least in 1997. That's all I wanted to</p> <p>25 know.</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A It is written down here on this piece of</p> <p>3 paper. That's what I can agree to.</p> <p>4 Q So the answer to my question is yes?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A I say it is written down on this piece of</p> <p>7 paper. This is not a sort of factual acknowledgment</p> <p>8 that this association was something Johnson and</p> <p>9 Johnson thought was scientific, rigorous, robust and</p> <p>10 legitimate.</p> <p>11 Q My question to you was, the information in</p> <p>12 this Johnson and Johnson document was information as</p> <p>13 of 1997 that Johnson and Johnson looked at and</p> <p>14 considered and was part of its business records,</p> <p>15 correct?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A This was written down on a Johnson and</p> <p>18 Johnson document. That, I can agree to.</p> <p>19 Q Can we agree that Johnson and Johnson is</p> <p>20 required to be honest and forthright when dealing</p> <p>21 with government agencies on product safety?</p> <p>22 MR. SMITH: Objection?</p> <p>23 A Yes.</p> <p>24 Q Can we agree that when relating</p> <p>25 information to the FDA on product safety, the whole</p>	<p>1 asbestos in Johnson and Johnson talc products, was a</p> <p>2 question that was repeatedly raised by the FDA</p> <p>3 beginning at least in the early '70s, correct?</p> <p>4 A The way you are saying it implies it was a</p> <p>5 specific question about Johnson and Johnson talc</p> <p>6 powders. It was not. It was about cosmetic talc in</p> <p>7 general.</p> <p>8 Johnson and Johnson was not</p> <p>9 questioning specifically about the integrity of our</p> <p>10 products per se by your question.</p> <p>11 Q So, is your testimony today that Johnson</p> <p>12 and Johnson -- excuse me, that the FDA never raised</p> <p>13 the issue with Johnson and Johnson as to whether</p> <p>14 there was any evidence of asbestos in any Johnson</p> <p>15 and Johnson products?</p> <p>16 A I didn't say that. The FDA asked us in</p> <p>17 the '70s, or we offered in the '70s, information on</p> <p>18 our testing of our products around the issue of</p> <p>19 asbestos.</p> <p>20 Q Did the FDA ask you whether there was any</p> <p>21 evidence of any amount of asbestos in any Johnson</p> <p>22 and Johnson cosmetic talc product?</p> <p>23 A I'm sure there was some question to that</p> <p>24 effect asked.</p> <p>25 Q And the answer by Johnson and Johnson was</p>
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<p>1 truth is required and not just part of the truth.</p> <p>2 Can we have agree to that?</p> <p>3 A The truth related to whatever the issue at</p> <p>4 hand is, yes, I'll agree to that.</p> <p>5 Q And it is considered a crime to</p> <p>6 intentionally mislead a government agency. Do you</p> <p>7 understand that?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes, I do.</p> <p>10 Q Now, am I correct whether there was</p> <p>11 asbestos in the Johnson and Johnson talc products</p> <p>12 was raised repeatedly by the FDA beginning in the</p> <p>13 early '70s?</p> <p>14 A It was raised. I don't know what that</p> <p>15 means.</p> <p>16 Q The issue was -- the question came up over</p> <p>17 and over again beginning in the 1970s and was posed</p> <p>18 to Johnson and Johnson, whether any Johnson and</p> <p>19 Johnson talc product contained asbestos. Can we</p> <p>20 agree with that?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A That's correct, and Johnson and Johnson</p> <p>23 talc never contained asbestos.</p> <p>24 Q We will get to that part. All I'm asking</p> <p>25 you, Ma'am, at this point is whether there was</p>	<p>1 always the same, correct, that is there is no</p> <p>2 evidence of any asbestos of -- scratch that.</p> <p>3 The answer provided by Johnson and</p> <p>4 Johnson was always the same, there's no evidence of</p> <p>5 any amount of any asbestos in any of Johnson and</p> <p>6 Johnson cosmetic products, correct?</p> <p>7 A There was no asbestos in Johnson and</p> <p>8 Johnson products, correct.</p> <p>9 Q Now, Johnson and Johnson specifically told</p> <p>10 the FDA that there was no asbestos or tremolite in</p> <p>11 Johnson's Baby Powder, correct?</p> <p>12 A Can you repeat that question?</p> <p>13 Q Yes, Ma'am. Johnson and Johnson told the</p> <p>14 FDA that there was no asbestos or tremolite in any</p> <p>15 Johnson's Baby Powder, correct?</p> <p>16 A I don't recall seeing that, no.</p> <p>17 Q 464. So you have in front of you a memo</p> <p>18 from July 27, 1971, about the special talc project</p> <p>19 and it memorializes a meeting that was held with</p> <p>20 Johnson and Johnson and the FDA, correct?</p> <p>21 A Yes.</p> <p>22 Q And you reviewed this in preparation for</p> <p>23 today's deposition?</p> <p>24 A Yes.</p> <p>25 Q The memo says a Dr. Weisler worked for the</p>

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<p>1 FDA, correct?</p> <p>2 A Yes.</p> <p>3 Q Wanted to know if tremolite or fibrous</p> <p>4 talc was found. We stated that our information is</p> <p>5 that no asbestos was found and that we will have a</p> <p>6 full, detailed report on the findings in about a</p> <p>7 week, correct?</p> <p>8 A Yes.</p> <p>9 Q Now, as a follow up to that, you, Johnson</p> <p>10 and Johnson told the FDA had that you had conclusive</p> <p>11 proof that there was no asbestos in Johnson's Baby</p> <p>12 Powder, correct?</p> <p>13 A I don't recall those exact words, but we</p> <p>14 did send extensive reports to the FDA about the</p> <p>15 testing qualification of the materials.</p> <p>16 Q 474 is a memo a couple weeks later,</p> <p>17 September 21, 1971, from Johnson and Johnson to the</p> <p>18 FDA. Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And what you state on the second page is,</p> <p>21 "It is seen that the data conclusively proves that</p> <p>22 Johnson's Baby Powder is free of asbestos," correct?</p> <p>23 A Yes.</p> <p>24 Q And that you further told the FDA that</p> <p>25 there was not ever a shred of evidence that there</p>	<p>1 Q 475 is another letter from 1973 written by</p> <p>2 Johnson and Johnson to the FDA, correct?</p> <p>3 A Yes.</p> <p>4 Q And it talks about Shower to Shower as a</p> <p>5 product, correct?</p> <p>6 A Yes.</p> <p>7 Q And what you state on the second page of</p> <p>8 your letter to the FDA is, "It should be noted that</p> <p>9 the talc in our medicated powder is from our Vermont</p> <p>10 mine source which has been exhaustively studied and</p> <p>11 reported on in various previous submissions. It was</p> <p>12 shown to be free of detectable asbestos by all</p> <p>13 available methods of analysis." Correct?</p> <p>14 A That is correct. This says it is from the</p> <p>15 mine source. It doesn't say it is a mine survey.</p> <p>16 That's where your question before was a little bit</p> <p>17 confusing.</p> <p>18 Q Johnson and Johnson told the FDA that "the</p> <p>19 source of the talc used in the powder from their</p> <p>20 Vermont mine was free of any detectable asbestos by</p> <p>21 all available analysis and methods." Correct?</p> <p>22 A You are misstating that. It says, "It</p> <p>23 should be noted that talc in our medicated powder is</p> <p>24 from our Vermont mine which has been exhaustively</p> <p>25 studied. It was shown to be free of detectable</p>
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<p>1 was asbestos in either Johnson's Baby Powder or</p> <p>2 Shower to Shower, correct?</p> <p>3 A That sounds familiar.</p> <p>4 Q Do I need to show you that document?</p> <p>5 A Sure, go ahead.</p> <p>6 Q 483. This is a memo concerning a meeting</p> <p>7 you had with the FDA in 1972, correct?</p> <p>8 A Yes.</p> <p>9 Q And what you told the FDA was that there</p> <p>10 wasn't a shred of evidence to support the idea that</p> <p>11 either Johnson and Johnson's Baby Powder or Shower</p> <p>12 to Shower contained any chrysotile asbestos,</p> <p>13 correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Correct.</p> <p>16 Q Not a shred of evidence?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A Yes.</p> <p>19 Q You told the FDA that there was absolutely</p> <p>20 no evidence of asbestos in any of the mines the baby</p> <p>21 powder came from using every method of analysis.</p> <p>22 You told them that, correct?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I don't recall saying that about the</p> <p>25 maintenance per se.</p>	<p>1 asbestos by all methods of analysis."</p> <p>2 It is unclear to me whether that's</p> <p>3 referring to the mine or the medicated powder. We</p> <p>4 have to go to the Pooley reports to determine what</p> <p>5 exactly was done in the Vermont mines.</p> <p>6 Q You don't know what this refers to as you</p> <p>7 sit here?</p> <p>8 A I'm saying I'm not sure of the "it." It</p> <p>9 is sentence structure whether the it refers to the</p> <p>10 powder or the mine.</p> <p>11 If we are going to talk about the</p> <p>12 mine, I would say that we should look specifically</p> <p>13 at the report of the mine.</p> <p>14 Q I'm going to do that later today. I want</p> <p>15 to know what you told the FDA and you represented.</p> <p>16 You understand that part of the purpose today is to</p> <p>17 determine whether Johnson and Johnson told the FDA</p> <p>18 the whole truth. You understand that, correct?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Yes, I do understand it. That's why I'm</p> <p>21 referring to that more comprehensive mine survey</p> <p>22 that was done.</p> <p>23 Q All I want to know now is exactly what</p> <p>24 Johnson and Johnson represented to the FDA. Then we</p> <p>25 will get to what they actually told the FDA. Do you</p>

<p style="text-align: right;">Page 94</p> <p>1 follow me?</p> <p>2 A No, I don't know the differences between</p> <p>3 represented and told.</p> <p>4 Q Let's focus on what Johnson and Johnson</p> <p>5 represented in terms of whether the talc mine or any</p> <p>6 of the products contained asbestos. That is what</p> <p>7 I'm focusing on, okay?</p> <p>8 A Okay.</p> <p>9 Q We are on the same page?</p> <p>10 A Um-hum.</p> <p>11 Q Is it your testimony that Johnson and</p> <p>12 Johnson told the FDA that there might be asbestos in</p> <p>13 the Vermont mines that it owned?</p> <p>14 A So we will have to go to the Pooley report</p> <p>15 to look at the mine. The products made from ore</p> <p>16 that came out of the Vermont mines is free of</p> <p>17 asbestos, based on the limits of detection of the</p> <p>18 methodology used. You are mixing two things,</p> <p>19 product and mines.</p> <p>20 Q No, I'm not mixing anything. You are</p> <p>21 mixing it in your answer. I'm asking you</p> <p>22 specifically did Johnson and Johnson represent to</p> <p>23 the FDA that the mines that it owned, that the talc</p> <p>24 came from, that was used in its products, did it tell</p> <p>25 the FDA that those mines were free of asbestos?</p>	<p style="text-align: right;">Page 96</p> <p>1 MR. SMITH: Objection.</p> <p>2 A My honest answer is we have a very</p> <p>3 comprehensive report here that we can look at and</p> <p>4 see exactly what was said, and that was sent to the</p> <p>5 FDA.</p> <p>6 Q Other than looking at the report, which we</p> <p>7 are going to get to, you don't know, you, Johnson</p> <p>8 and Johnson, don't know as you sit here today</p> <p>9 whether you ever represented to the FDA specifically</p> <p>10 that there's no evidence of asbestos in the mines</p> <p>11 used to manufacture baby powder or Shower to Shower?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I don't know what -- I keep giving, you</p> <p>14 have the answer, which is in the report that</p> <p>15 went to the FDA, and we can look at that point and</p> <p>16 see exactly what it says.</p> <p>17 Q Does the report, Ma'am, as you sit here</p> <p>18 today, do you have any evidence, do you have any</p> <p>19 recollection of seeing a report to the FDA that</p> <p>20 admitted that there was asbestos in any of the mines</p> <p>21 used to manufacture baby powder or Shower to Shower?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Would you like to look at the report?</p> <p>24 Q I'm asking you what you know, Ma'am. We will</p> <p>25 get to the reports later. Do you have any</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. SMITH: Objection.</p> <p>2 A We sent the report from Dr. Pooley of the</p> <p>3 Italian mines and Vermont mines to the FDA. We will</p> <p>4 have to go to those reports to see exactly what it</p> <p>5 says. I have those here, I'm happy to pull those</p> <p>6 out.</p> <p>7 Q Ma'am, I'm asking you a very specific</p> <p>8 question. Did Johnson and Johnson represent to the</p> <p>9 FDA that the mines that were used to make Johnson's</p> <p>10 Baby Powder or Shower to Shower were free of</p> <p>11 asbestos? That is my question. Did you make that</p> <p>12 representation?</p> <p>13 A I don't recall any specific statement to</p> <p>14 that effect, but I do know that we sent</p> <p>15 comprehensive surveys of the mines that were used to</p> <p>16 the FDA and I have those here and I'm happy to review</p> <p>17 them.</p> <p>18 Q I'm going to do that with you. All I want</p> <p>19 to know, the only thing I'm focusing on is what you</p> <p>20 told the FDA about whether the mines that you own</p> <p>21 that were used for baby powder and Shower to Shower,</p> <p>22 whether you ever told them they had asbestos anywhere</p> <p>23 in the mine, and your answer is what?</p> <p>24 MR. SMITH: Objection.</p> <p>25 Q You don't know?</p>	<p style="text-align: right;">Page 97</p> <p>1 independent memory?</p> <p>2 A I have an independent memory that reports</p> <p>3 are complex and they have multiple testing in them</p> <p>4 and you have to go to the conclusion to see what the</p> <p>5 report said to understand the meaning of what was</p> <p>6 communicated between J and J and the FDA.</p> <p>7 Q Do we agree, as you sit here, you don't</p> <p>8 have any independent knowledge of what was</p> <p>9 represented to the FDA about whether the mine that</p> <p>10 was used to manufacture baby powder or Shower to</p> <p>11 Shower had asbestos in it?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q You have no independent recollection?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A My recollection is based on the report</p> <p>16 that was sent to the FDA, which I would be very</p> <p>17 happy to review with you.</p> <p>18 Q Without looking at that report, what is</p> <p>19 your recollection?</p> <p>20 A My recollection is it is a very complex</p> <p>21 report, but that material there comes out of that</p> <p>22 mine that is used to make baby powder does not</p> <p>23 contain asbestos.</p> <p>24 MR. SMITH: What time do we want to</p> <p>25 break for lunch?</p>

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<p>1 MR. PLACITELLA: Why don't you give 2 me another fifteen minutes and then we can break. 3 4 Q Am I correct you told the FDA that there 5 isn't a single instance where a test result showed 6 there was chrysotile asbestos in any Johnson and 7 Johnson product? 8 A No product released to the market ever 9 contained chrysotile asbestos. 10 Q My question is, did you affirmatively 11 represent to the FDA that there is not a single 12 instance, not a single report of chrysotile in any 13 of the Johnson and Johnson products? 14 A We have said over and over again there's 15 no asbestos in our products, so I would say that 16 includes chrysotile asbestos. 17 Q A single instance? Not one? 18 A No product has been released to the market 19 there contains a single instance of asbestos. 20 Q Now, you understand that tremolite is 21 something known as an amphibole? 22 A Yes. 23 Q Did you represent specifically to the FDA 24 that there are no amphiboles or serpentine materials 25 ever detected in a Johnson and Johnson product?</p>	<p>1 been found in any testing ever. Correct? 2 MR. SMITH: Objection. 3 A This refers to -- hold on, let me find the 4 page. This refers to the worldwide survey for body 5 powders. This is off the shelf Johnson and Johnson 6 body powders that are collected all over the 7 world and tested for asbestos and that's 8 correct, that no asbestos has ever been found in 9 those materials. 10 Q Ever? 11 A Referring specifically to the worldwide 12 surveys of Johnson and Johnson baby powders that are 13 taken off the shelf and tested for asbestos, and 14 during that program no asbestos has be detected in 15 materials that is out for consumers to buy. 16 Q So no matter where they got the asbestos 17 anywhere in the world, it is Johnson and Johnson's 18 position that there's never been a single test 19 showing that there's asbestos in the Johnson and 20 Johnson products, correct? 21 MR. SMITH: Objection. 22 A So you said we went around the world to 23 get asbestos? We went around the world to get 24 Johnson and Johnson baby products off the shelf, 25 test for asbestos and those have not shown asbestos</p>
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<p>1 A No, because that wouldn't be correct. 2 Q Exhibit 60 is the submission that your 3 trade association gave to the FDA, which included a 4 letter from Johnson and Johnson, correct? 5 A It is a little hard to read. It is so 6 tiny. I'm looking. Give me one minute, please. 7 Yes, I've seen this. 8 Q And can you go to the part of the 9 submission that is authored by Johnson and Johnson, 10 the March 19, 1976 letter. 11 A I see March 14th. Hold on. 12 Q March 15th. 13 A March 15th. You said 19th. 14 Q Okay. And what you say to the FDA, no 15 amphibole materials have been detected, correct? 16 A That's what it says beginning in October 17 1973 to whatever date in 1976. 18 Q Right. Now, I'll show you 492. 492 is 19 your March 17, 2016 letter to the FDA on Johnson and 20 Johnson letterhead, correct? 21 A Yes. 22 Q And in that letter, what you did is in the 23 face of lawsuits and verdicts, you went back to the 24 FDA and told them, again, that from the perspective 25 of Johnson and Johnson, no asbestos structures have</p>	<p>1 in that material that is out on the shelf for 2 consumers to buy. 3 Q That's my question. It is your position 4 that no matter where you go in the world, if you 5 tested the Johnson Baby Powder, it has no evidence 6 of asbestos and never did. That's your position, 7 correct? 8 MR. SMITH: Objection. 9 A That is the facts related to this 10 worldwide survey we shared with the FDA in March of 11 2016. 12 Q It had no asbestos and never did, correct? 13 A It says no asbestos was found in that 14 worldwide survey. 15 Q And never did? 16 A It does not say never did. 17 Q Well, was it ever? 18 A Was it ever what? 19 Q Found asbestos in any Johnson's Baby 20 Powder? 21 A Not production product that's on the shelf 22 for consumers to buy, no. 23 Q So it is Johnson and Johnson's position as 24 we are sit here today that no testing ever showed 25 any amounts of any asbestos in any Johnson and</p>

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<p>1 Johnson consumer product, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A When you refer to Johnson and Johnson</p> <p>4 consumer product, that is product that has been</p> <p>5 released to the market. No, there's not been</p> <p>6 asbestos in that product that has been tested by</p> <p>7 legitimate means.</p> <p>8 Q When you stay legitimate means, what do</p> <p>9 you mean by that?</p> <p>10 A Some individuals have bought products off</p> <p>11 of Ebay and other sources and tested them and</p> <p>12 claimed to have found asbestos, and I believe that</p> <p>13 is incorrect methodology and unreliable test</p> <p>14 results.</p> <p>15 Q And you are competent to testify about the</p> <p>16 methodology used by experts testing asbestos?</p> <p>17 A No, but I'm competent to testify if you</p> <p>18 buy something on Ebay that's been opened in an</p> <p>19 environment that is uncontrolled, you cannot rely on</p> <p>20 those results.</p> <p>21 Q What about testing products that are in</p> <p>22 Johnson and Johnson's historical files? Is that a</p> <p>23 legitimate methodology?</p> <p>24 A It is a legitimate source of material, but</p> <p>25 the methodology is another issue.</p>	<p>1 happy, welcome to come look at them? Did you ever</p> <p>2 tell them that?</p> <p>3 A In effect, we have.</p> <p>4 Q And who did you tell specifically that?</p> <p>5 And who said that?</p> <p>6 A Until June of this past year a number of</p> <p>7 individuals, myself included, met with the FDA and</p> <p>8 discussed test results and asbestos testing in our</p> <p>9 quality assurance system that starts qualifying of</p> <p>10 the mines and goes through multiple testing to the</p> <p>11 finished products, and that they are more than</p> <p>12 welcome to see any of those tests.</p> <p>13 They didn't want to see the tests.</p> <p>14 They wanted our specifications and our methodology</p> <p>15 and so forth, all of which was sent to them.</p> <p>16 Q So before -- did you say this year?</p> <p>17 A You asked me if we ever had --</p> <p>18 Q I want to get the date right. This year?</p> <p>19 A 2018.</p> <p>20 Q So before June of 2018, have you ever made</p> <p>21 all of your test results available for inspection by</p> <p>22 the FDA?</p> <p>23 A The FDA can inspect us at any time and we</p> <p>24 would have certainly worked with them and cooperated</p> <p>25 to make whatever tests results they wanted</p>
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<p>1 Q One more and we will break for lunch.</p> <p>2 498 comes from an advertisement that</p> <p>3 you ran in December of last year all over the United</p> <p>4 States. You have seen this before, correct?</p> <p>5 A Yes.</p> <p>6 Q You say, "We know that we have always</p> <p>7 cooperated fully and openly with the FDA and other</p> <p>8 regulators and have given them full access to our</p> <p>9 testing, our talc testing results." Do you see</p> <p>10 that?</p> <p>11 A Yes.</p> <p>12 Q That means you gave them all the test</p> <p>13 results in your possession?</p> <p>14 A Full access. We have not sent them every</p> <p>15 single test result. I don't think they would</p> <p>16 appreciate that very much.</p> <p>17 Q So who decided what test results were</p> <p>18 going to be sent to the FDA and which ones were not?</p> <p>19 Who made that decision?</p> <p>20 A Full access means that if there's any</p> <p>21 issue to be discussed where test results would be</p> <p>22 helpful, they absolutely would share those results</p> <p>23 with the FDA.</p> <p>24 Q Did you ever tell the FDA that we have</p> <p>25 other test results we didn't send you, but you are</p>	<p>1 available to them.</p> <p>2 Q Ma'am, before June of 2018, had you ever</p> <p>3 told the FDA that you had test results related to</p> <p>4 asbestos in talc that you did not provide them?</p> <p>5 A No, not that I know of.</p> <p>6 Q You also say in your advertisement, "We</p> <p>7 know that we did not hide anything. Our openness and</p> <p>8 collaboration with the FDA and regulatory agencies</p> <p>9 is well documented." Correct?</p> <p>10 A Correct.</p> <p>11 Q The books you have in front of you, let's</p> <p>12 identify them and we will go take a break for lunch</p> <p>13 and I'll look at them at lunchtime. Okay?</p> <p>14 So tell me what is in each of the</p> <p>15 books generally that you have in front of you.</p> <p>16 A So P-3 is volume 1 and contains</p> <p>17 communications back and forth between Johnson and</p> <p>18 Johnson and the FDA and some other contextual</p> <p>19 documents are included as well.</p> <p>20 Volume 2 is the March 2016</p> <p>21 communication that we sent to the FDA and all of the</p> <p>22 associated attachments. In addition, there's a</p> <p>23 July 2018 communication in volume number 2.</p> <p>24 Volume 3 are contextual documents</p> <p>25 that indicate what was going on at different points</p>

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<p>1 in time during the history of talc and asbestos 2 starting in the late '60s up until present day, 3 giving you context for understanding the development 4 of asbestos testing, citizens petitions and other 5 related events.</p> <p>6 Q That's it?</p> <p>7 A That's it.</p> <p>8 Q In these three volumes, does that include 9 all the information that you provided to the FDA 10 concerning the testing of Johnson and Johnson talc 11 for asbestos?</p> <p>12 A As far as I'm aware, yes, it does.</p> <p>13 MR. PLACITELLA: This is a good place 14 to take a break.</p> <p>15 THE VIDEOGRAPHER: The time is 16 approximately 12:32 p.m. We are going off the 17 record.</p> <p>18 (Luncheon recess taken)</p> <p>19</p> <p>20 THE VIDEOGRAPHER: We are back on the 21 record. The time is approximately 1:12 p.m.</p> <p>22</p> <p>23 CONTINUED DIRECT BY MR. PLACITELLA:</p> <p>24</p> <p>25 Q Dr. Nicholson, I asked this morning, and I</p>	<p>1 Q There's no testing done on Johnson and 2 Johnson Baby Powder related to the 1980s, correct?</p> <p>3 A Correct. Then there's -- one last 4 document, which is tab 13, which is the McCrone 5 letter that says that for the previous fifteen 6 years, and this letter is dated May 1987, that they 7 had been testing routinely material for a number of 8 companies, including Johnson and Johnson over the 9 years, and have the product is free of asbestos, 10 second to the last line. That is not FDA, but 11 that's an independent organization testing talc for 12 industry.</p> <p>13 Q Right. But they were paid by Johnson and 14 Johnson.</p> <p>15 A They were.</p> <p>16 Q So my question this morning was, you don't 17 have any evidence, as you sit here today, of any 18 test run by the FDA of Johnson talc products from a 19 Vermont source after 1979, correct?</p> <p>20 A Correct. The FDA didn't do their own 21 testing. They, too, used outside sources.</p> <p>22 Q But there was no testing by any outside 23 source hired by the FDA of Vermont based products 24 after 1979, correct?</p> <p>25 A That is correct. We have a calculations</p>
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<p>1 know you looked it over at a break, I asked you 2 questions about the FDA itself testing for 3 Vermont sourced products, and you said you believe 4 there was testing in the '84, '86, but you weren't 5 sure what they tested for. Did you find what you 6 were referencing?</p> <p>7 A I found three different things, and so one 8 is a 1986 FDA petition denial, which is more 9 mathematical analysis of some theoretical exposure 10 limits.</p> <p>11 So the one thing of importance was 12 around the exposure risk assessment.</p> <p>13 Q I'm familiar with that document, but that 14 had nothing to do with the physical testing of a 15 Johnson and Johnson product for asbestos, correct?</p> <p>16 A That is correct. Then there was the 17 Boundy Study, which did review --</p> <p>18 Q That's on what tab and what exhibit?</p> <p>19 A This is tab 9 of P-5. This refers to 20 NIOSH, which is the National -- I don't remember 21 what NIOSH stands for.</p> <p>22 This is from Maryanne Boundy and 23 others from Environmental Health Sciences from 24 Harvard. This is in the late '70s. They looked at 25 bulk Vermont talc.</p>	<p>1 by FDA and the McCrone letter saying talc is 2 free from asbestos for fifteen years. But you are 3 correct, FDA, not until 2009, did a survey of 4 cosmetic talc.</p> <p>5 Q And when the FDA did their survey of 6 cosmetic talc in 2009, Johnson and Johnson was no 7 longer using a Vermont mine as the source for its 8 cosmetic talc, correct?</p> <p>9 A That's correct. In 2003 we switched to 10 China.</p> <p>11 Q So from 1979 until any time thereafter, 12 the FDA never did a test to determine whether the 13 Johnson and Johnson talc contained asbestos that was 14 sourced from a Vermont mine, true?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A So FDA did not do a test of Johnson and 17 Johnson product. That is correct, but Johnson and 18 Johnson was testing their product, McCrone was 19 testing the product.</p> <p>20 We know it was free of asbestos, but 21 you are correct, Johnson and Johnson did not test 22 the product that I'm aware of.</p> <p>23 Q So without everything else stuffed in, all 24 I want to know is as we sit here today can we agree 25 that there was no testing done by the FDA of any</p>

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<p>1 Johnson and Johnson product that came from a Vermont 2 mine after 1979?</p> <p>3 A Not that I'm aware of that we have 4 evidence in these documents.</p> <p>5 Q So any time after 1979, any test results 6 that were considered by the FDA were done for 7 Johnson's Baby Powder, were done by Johnson and 8 Johnson or the experts that it hired, correct?</p> <p>9 A I can't speak to others outside of that 10 circle, for example, academics that did testing on 11 product that would have been Johnson and Johnson 12 product. But in the documents prepared for today, I 13 have just the McCrone letter saying free from 14 asbestos and that includes Vermont talc.</p> <p>15 Q So from your perspective in the FDA 16 assessing the safety of the Johnson and Johnson 17 product in terms of whether it ever contained 18 asbestos, the only test result you can point to 19 after 1979 is the McCrone letter that you 20 referenced?</p> <p>21 A Well, we have internally thousands and 22 thousands of test results.</p> <p>23 Q That wasn't my question, Ma'am. My 24 question was test results considered by the FDA and 25 assessing the safety of the Johnson and Johnson's</p>	<p>1 I'm trying to be very specific in my answer.</p> <p>2 Q The answer is that for Vermont talc, the 3 only test you gave to the FDA and that you 4 understand was considered by the FDA was the 1987 5 McCrone letter in terms of whether the Johnson 6 product was asbestos free, correct?</p> <p>7 A That the FDA had, that's correct, but 8 again, we were following the J41 standard.</p> <p>9 Q We will get to that. Let me ask you some 10 more questions about the binder before we get to the 11 standard.</p> <p>12 The binder, I don't know which one it 13 was, had an expert report from a lawsuit from a Mr. 14 Bailey. You gave that to the FDA?</p> <p>15 A No. The reason we included that, you 16 recall I explained about the binders is that this 17 was also to create context so those communications 18 and why would we been talking about any given thing 19 would be understood.</p> <p>20 Dr. Bailey gave a very comprehensive 21 review of what was done and how things progressed 22 from the '60s through to more recent times. That's 23 why it was included.</p> <p>24 Q But his report was never given to the FDA?</p> <p>25 A Not that I'm aware of.</p>
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<p>1 talc products, the only test results that you have 2 that was supplied to the FDA and considered by the 3 FDA after 1979 was the McCrone 1987 letter, true?</p> <p>4 A So I'm confused by your question because 5 it was the 2009 survey that included Johnson and 6 Johnson baby products and raw materials.</p> <p>7 Q Let me rephrase it then. It is my fault. 8 From 1979 forward, the FDA had no 9 information in its possession that you are aware of 10 concerning Johnson's talc products sourced from a 11 Vermont mine on the issue of asbestos content, other 12 than the McCrone letter from 1987, correct?</p> <p>13 A Well, they had information we would have 14 been following the J41 standard that basically 15 required us to test everything for asbestos. So we 16 were in compliance with the standard and therefore, 17 testing regularly for asbestos.</p> <p>18 Q Ma'am, my question to you is after 1979, 19 the only document that you gave to the FDA to 20 support the proposition that Vermont sourced talc 21 products were asbestos free was the McCrone letter 22 from 1987, true?</p> <p>23 A That I recall related to Vermont talc.</p> <p>24 Q So the answer is yes?</p> <p>25 A You put so many qualifications in there,</p>	<p>1 Q So if we wanted to be very specific now, 2 as to what scientific information you provided to 3 the FDA on the issue of whether there was ever 4 asbestos found in any Johnson and Johnson talc 5 product, they are included in what binder?</p> <p>6 A They are in this binder.</p> <p>7 Q When you say this binder, be specific.</p> <p>8 A Volume 1, P-3.</p> <p>9 Q So we don't have to worry ourselves, binder 10 2 or 3 on this specific topic of testing information 11 that you gave to the FDA concerning asbestos and 12 Johnson talc, correct?</p> <p>13 A Except volume 2 contains the entirety of 14 the two most recent communications to the FDA.</p> <p>15 Q So let me be specific then. Other than 16 the communications you had with the FDA after 2017, 17 all of the scientific information that you provided 18 to the FDA concerning whether the Johnson's Baby 19 Powder contained asbestos at any point in time, or 20 Shower to Shower, is contained in volume 1. Is that 21 fair?</p> <p>22 A Yes.</p> <p>23 Q Except you said 2017, not 2016.</p> <p>24 Q 2016. Okay.</p> <p>25 Now, 457 is a document, looks like</p>

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<p>1 from 1977, listing all of the information you 2 supplied to the FDA as of 1977. Is that true? 3 A That's true. And this is contained in 4 this binder. 5 MR. SMITH: Which binder? 6 A Volume 1, P-3. 7 Q So everything that is on that list is 8 contained in binder number 1? 9 A Everything we could find in our records is 10 contained herein. There are some documents that we 11 can note that we couldn't find that were referenced in 12 other material with the original documents was not 13 in our records and could not be located. 14 Q Did somebody go back and look for the 15 paper and see if there was a paper file of the 16 original document? 17 A Yes. 18 Q That doesn't exist? 19 A Not that we have found. 20 Q Can we agree that no one at the FDA knew 21 more about the flaws or shortcomings in the asbestos 22 testing methods than Johnson and Johnson and the 23 experts that it hired? 24 MR. SMITH: Objection. 25 A I can't speak to what the FDA knew or</p>	<p>1 1973, attended by Johnson and Johnson. If you go to 2 the page where you see where it says, meeting of talc 3 group March 21, 1973 and it says Dr. Ashton from 4 Johnson and Johnson was present? 5 A Yes. 6 Q It talks about what Dr. Ashton discussed 7 at the meeting on the third page. It says Dr. 8 W.H. Ashton, J and J, began discussion of 9 methodology for determining asbestos or fibers by 10 reviewing J and J experience with different 11 instruments. Least sensitive is optical microscope. 12 Next in order of increasing 13 sensitivity and cost and difficulty to run are x-ray 14 scan, x-ray step scan, electron scan, electron 15 differential scan and DPA differential thermal 16 atomizer. Do you see that? 17 A Yes. 18 Q And what Johnson and Johnson ultimately 19 urged the FDA to adopt what was the two worst in 20 this list, right, the least sensitive, the optical 21 microscope the X-ray diffraction, correct? 22 MR. SMITH: Objection. 23 A You are mischaracterizing that. You are 24 looking at them as individual tests, and it has been 25 discussed in numerous documents that using multiple</p>
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<p>1 didn't know. 2 Q Do you understand that in the process of 3 trying to come up with a way to reliably test for 4 asbestos, that the FDA wanted a method that had a 5 sensitivity greater than 1 percent. You know that, 6 correct? 7 MR. SMITH: Objection. 8 A At one point of the discussions that 9 one percent number was contemplated. The actual 10 sensitivity is significantly lower than that. 11 Q Am I correct that Johnson and Johnson 12 recommended to the FDA a testing method that Johnson 13 and Johnson knew would not find amphiboles, 14 including tremolite, at low levels? 15 A I don't know what you are referring to. 16 Q Well, am I correct that of all the testing 17 methods that were available for the determination of 18 whether there was asbestos or tremolite in Johnson 19 and Johnson talc, Johnson and Johnson urged the FDA 20 to pick the two worst methods for figuring that out? 21 A That is not correct. 22 MR. SMITH: Objection. 23 Q 489. I want to show you a document marked 24 April 18, 1973, business records of Whittaker, Clark 25 and Daniels memorializing a meeting of March 21,</p>	<p>1 tests, the correct multiple tests together, is what 2 gives you the best results. So you are 3 mischaracterizing what is being stated. 4 Q I'm not. All I'm asking you is ultimately 5 the two tests in combination that Johnson and 6 Johnson recommended that the FDA use were the two 7 least sensitive tests, according to Dr. Ashton, that 8 is, the optical microscope and the X-ray diffraction 9 method, right? 10 A Wrong. You are mischaracterizing that. 11 You have said in combination and then in combination 12 they are the best method. That's why they are in 13 the J41. 14 Q What Johnson and Johnson recommended was 15 first you use the X-ray diffraction and then, if 16 that comes up positive, you then you use the optical 17 microscope, correct? 18 A That's how you figure out if you have 19 asbestos in your sample. A step one screening. 20 Q They used the two least sensitive methods 21 as articulated by Dr. Ashton in this document, 22 correct? 23 A Not correct. You are totally 24 misunderstanding what is being said. 25 Q I don't think so. We are going to get to</p>

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<p>1 that.</p> <p>2 130 is the J41 method we have been</p> <p>3 discussing, correct?</p> <p>4 A Yes.</p> <p>5 Q What it does is, it uses X-ray diffraction</p> <p>6 and the optical microscope, correct?</p> <p>7 A Yes.</p> <p>8 Q And it acknowledges that the other tests</p> <p>9 available are more sensitive for finding amphibole</p> <p>10 minerals, but for economic reasons, they</p> <p>11 weren't recommended, right? That's what it says?</p> <p>12 A Where are you looking?</p> <p>13 Q Is says, "The method which has been</p> <p>14 adopted for the detection of amphibole minerals in</p> <p>15 cosmetic talc is generally accepted method of x-ray</p> <p>16 diffraction. Methods which appear in the literature</p> <p>17 for the detection of fibers amphibole, such as</p> <p>18 transmission electron microscope, diffraction and</p> <p>19 electron microbe have also been considered since</p> <p>20 they are capable of a lower level of detection than</p> <p>21 by x-ray diffraction." Did I read that correctly?</p> <p>22 A You did, but the next sentence says they</p> <p>23 suffer from drawbacks and the amount of material</p> <p>24 they look at is quite small.</p> <p>25 You have to measure sensitivity and</p>	<p>1 Lee, from your office, correct?</p> <p>2 A That is correct.</p> <p>3 Q And what is concluded at the bottom is</p> <p>4 test and verified CTFA method J 41 for this purpose,</p> <p>5 assurance that method is accurate, reliable and</p> <p>6 practical. He then reported the objectives have not</p> <p>7 been achieved. Do you see that?</p> <p>8 A I see he reported that, yes.</p> <p>9 Q If you look at the second page, it talks</p> <p>10 about using the CTFA method with spiked tremolite.</p> <p>11 In other words, they actually put the tremolite in</p> <p>12 the -- they actually put tremolite and spiked it.</p> <p>13 Do you see that?</p> <p>14 A I don't see that.</p> <p>15 Q Do you see where it says CTFA tremolite</p> <p>16 spiked talc where they took the talc and spiked it</p> <p>17 with tremolite?</p> <p>18 A Tremolite is an asbestos. That's what I'm</p> <p>19 trying to understand here.</p> <p>20 Q Ma'am, I'm saying to you that the J41</p> <p>21 method failed to find amphiboles including tremolite</p> <p>22 that was known to be tremolite by your own testing,</p> <p>23 correct?</p> <p>24 A If you give me a second to review the</p> <p>25 whole document. I think it is easy to misinterpret</p>
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<p>1 specificity and combine methods to get the right</p> <p>2 answer.</p> <p>3 Q What it says is, "The time for analysis</p> <p>4 the expertise required and the expense of the</p> <p>5 equipment." Correct?</p> <p>6 A That's what it says.</p> <p>7 Q So, the J41 method selected was a</p> <p>8 combination of x-ray diffraction first, correct?</p> <p>9 A Correct.</p> <p>10 Q Intended to find amphiboles, not</p> <p>11 chrysotile asbestos, correct?</p> <p>12 A You can rule out amphiboles with x-ray</p> <p>13 diffraction. That's correct.</p> <p>14 Q This was the method that J and J urged the</p> <p>15 FDA to adopt, correct?</p> <p>16 A That is correct.</p> <p>17 Q When Johnson and Johnson ran this method</p> <p>18 on samples known to have asbestos in them, the</p> <p>19 method did not find asbestos, correct?</p> <p>20 A Not correct.</p> <p>21 Q 148 are minutes from your trade</p> <p>22 association from May 1977, which is after you came</p> <p>23 up with the J41 specification, correct?</p> <p>24 A Correct.</p> <p>25 Q And present at that meeting was George</p>	<p>1 if you only look at a line or two. I would prefer a</p> <p>2 minute to look at the entire document.</p> <p>3 Q You didn't look at that in preparation for</p> <p>4 today?</p> <p>5 A I've seen this before.</p> <p>6 Q Okay.</p> <p>7 A I would like to look at, if you don't</p> <p>8 mind.</p> <p>9 MR. SMITH: You can.</p> <p>10 A Go ahead.</p> <p>11 Q So let's go back to the front page. It</p> <p>12 talks about the purpose of the test was to determine</p> <p>13 whether or not any 1976 production of major</p> <p>14 commercial talc products contained asbestiform</p> <p>15 amphibole contaminants. Test and verify CTFA method</p> <p>16 J41 for this purpose. Assurance that the method is</p> <p>17 accurate, reliable and practical.</p> <p>18 The report is that the objectives</p> <p>19 were not reached, and immediately after that, are</p> <p>20 the test results, correct?</p> <p>21 A That is correct.</p> <p>22 Q It says that they took tremolite, which</p> <p>23 was a talc, talc which was spiked with tremolite and</p> <p>24 talc that was spiked with anthophyllite and they let a</p> <p>25 number of different laboratories to run tests on</p>

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<p>1 that. Do you see that?</p> <p>2 A I do.</p> <p>3 Q What it shows is from looking for</p> <p>4 tremolite, only one laboratory found tremolite using</p> <p>5 the CTFA method and six did not. Do you see that?</p> <p>6 A I do.</p> <p>7 Q That was tremolite that was spiked, in</p> <p>8 other words, they put the tremolite in the talc,</p> <p>9 correct, so you could see if they could find it,</p> <p>10 right?</p> <p>11 A That is correct.</p> <p>12 Q When they used the CTFA method, six out of</p> <p>13 seven couldn't find it using the CTFA method,</p> <p>14 correct?</p> <p>15 A Six out of seven reported a negative test.</p> <p>16 That's correct.</p> <p>17 Q Now, you are aware, are you not, that</p> <p>18 internally Johnson and Johnson actually wrote down</p> <p>19 that the CFTA method was not good enough and not</p> <p>20 sensitive enough to find low levels of tremolite.</p> <p>21 You are aware of that, right?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Are we still talking about this document?</p> <p>24 Q No, I'm asking you another question.</p> <p>25 A Okay.</p>	<p>1 was in cosmetic talc, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A So TEM was discussed extensively during</p> <p>4 the meeting and we are going back to that document</p> <p>5 you just showed me. But practical, reliable and</p> <p>6 sensitive. So if people did not have the machine for</p> <p>7 the testing, it could not be suggested and adopted</p> <p>8 as a universal standard for the industry.</p> <p>9 Q Yes, Ma'am. The answer to my question is</p> <p>10 Johnson and Johnson did not recommend to the FDA</p> <p>11 that the standard that should be adopted for testing</p> <p>12 talc for asbestos was TEM, correct?</p> <p>13 A I can't answer that question because it</p> <p>14 was a scientific discussion of many methods and</p> <p>15 there were multiple participants in the</p> <p>16 conversation.</p> <p>17 Johnson and Johnson wasn't in a</p> <p>18 position to have a definitive recommendation, but</p> <p>19 rather come to a consensus agreement with FDA and</p> <p>20 the industry partners.</p> <p>21 So you are asking me if they had</p> <p>22 a separate opinion. I have not seen any</p> <p>23 documents to that effect, but I've seen other</p> <p>24 documents discuss all of the various methods that</p> <p>25 were available, like the one we talked about a</p>
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<p>1 Q You are aware that internally Johnson and</p> <p>2 Johnson had discussions where they acknowledged that</p> <p>3 the CFTA, J41 method was not good enough for the</p> <p>4 detection of low levels of tremolite, correct?</p> <p>5 A It is the CTFA, not the CTFA and we always</p> <p>6 use transmission electron microscopy adjunct, so that</p> <p>7 may have been discussed and perhaps validated while</p> <p>8 we continue to this day to use test TEM, which is</p> <p>9 the most sensitive method.</p> <p>10 Q You didn't recommend to the FDA to use</p> <p>11 TEM, your recommendation to the FDA was for the J41</p> <p>12 method, correct?</p> <p>13 A The Cosmetics Toiletry and Fragrance</p> <p>14 Association recommended the J41. We continued to do</p> <p>15 TEM.</p> <p>16 One of the major limitations at the</p> <p>17 time is that TEM was not universally available.</p> <p>18 We, however, had that equipment. We used all of</p> <p>19 that equipment all the time.</p> <p>20 Q That wasn't my question, please. We've</p> <p>21 got to finish this deposition, so if you could just</p> <p>22 answer my question.</p> <p>23 My question is this, that Johnson and</p> <p>24 Johnson did not recommend to the FDA that TEM be</p> <p>25 used for the testing to determine whether asbestos</p>	<p>1 minute ago.</p> <p>2 Q What was recommended by Johnson and</p> <p>3 Johnson and its trade association for the analysis</p> <p>4 of asbestos in talc was the CFTA J41 method,</p> <p>5 correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A It is the CTFA J41 method, and the</p> <p>8 document you showed me a minute ago, the industry</p> <p>9 was continuing to look at that method and refining</p> <p>10 it to make sure it was accurate, reliable and</p> <p>11 practical.</p> <p>12 So not at that time did we definitively</p> <p>13 say this is the one and only standard, we are not</p> <p>14 going to evolve our thinking. This was something</p> <p>15 being actively tested and refined in 1977 and has</p> <p>16 been revisited since then. So I'm not sure what you</p> <p>17 are implying with the question.</p> <p>18 Q You were still using it in 1995, right?</p> <p>19 A Who is we?</p> <p>20 Q The CTFA Method. Johnson and Johnson.</p> <p>21 A We used that method. It is an industry</p> <p>22 standard and in addition, we do TEM testing.</p> <p>23 Q And internally you acknowledge, did you</p> <p>24 not, that the CTFA method was not sensitive enough</p> <p>25 to find low levels of tremolite. You acknowledge</p>

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<p>1 that.</p> <p>2 A That's true. Every test method has a limit</p> <p>3 of detection, but we still use TEM, which increases</p> <p>4 our abilities in sensitivity of our testing.</p> <p>5 Q Ma'am, all I'm asking you is internally</p> <p>6 you acknowledged, you, Johnson and Johnson, that the</p> <p>7 CTFA J41 method was not sensitive enough to find low</p> <p>8 levels of tremolite, correct?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A Every test method, combination of test</p> <p>11 methods has their limits of detection, so that would</p> <p>12 have been acknowledged by FDA, CTFA, Johnson and</p> <p>13 Johnson and many others.</p> <p>14 Q So the answer to my question is internally</p> <p>15 Johnson and Johnson acknowledged that the CTFA J41</p> <p>16 method was not sensitive enough to find low levels</p> <p>17 of tremolite when testing the powder, correct?</p> <p>18 A First of all, tremolite is not asbestos.</p> <p>19 Second of all, the CTFA method, every method of</p> <p>20 detection does have its limits. So everyone would</p> <p>21 have acknowledged that, including J and J.</p> <p>22 Q In fact, when you were testing your</p> <p>23 products in Great Britain, you specifically rejected</p> <p>24 using the CTFA method, didn't you?</p> <p>25 A I have not reviewed that topic in</p>	<p>1 forward in this written by Dr. Pooley?</p> <p>2 A Yes.</p> <p>3 Q Do you see it actually says, and I blew it</p> <p>4 up so you can read it. In the second paragraph,</p> <p>5 "Incidents of disease among talc workers has been</p> <p>6 closely linked to the mineralogic impurities found in</p> <p>7 raw material such as asbestos minerals and quartz."</p> <p>8 Do you see that?</p> <p>9 A I do.</p> <p>10 Q Was that fact ever discussed with Dr.</p> <p>11 Hopkins by you internally at Johnson and Johnson?</p> <p>12 A No, because there's not asbestos contained</p> <p>13 in any of the cosmetic talc mines that went into our</p> <p>14 cosmetic products.</p> <p>15 Q We will get to that. Do you see in Dr.</p> <p>16 Hopkins' memo, 5.2 fibrous amphiboles, where</p> <p>17 he states, "the inhalation hazards of fibrous minerals</p> <p>18 have long been recognized. The CTPA view is that</p> <p>19 fibrous minerals should not be detectable in</p> <p>20 cosmetic talc by state of the art methods."</p> <p>21 And then he goes on to say, "However,</p> <p>22 in order to eliminate any hazards to the consumer,</p> <p>23 which might arise from the need to interpret fiber</p> <p>24 and shape dimensions and to facilitate routine</p> <p>25 screening, the CTPA view is that if an amphibole is</p>
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<p>1 preparation for today.</p> <p>2 Q You spoke to Dr. Hopkins, correct?</p> <p>3 A We didn't discuss that particular issue.</p> <p>4 Q Dr. Hopkins never told that you he</p> <p>5 actually wrote a memo indicating that in Great</p> <p>6 Britain they recommended against using the CTFA</p> <p>7 method because it wasn't sensitive enough?</p> <p>8 A I haven't reviewed that to prepare for</p> <p>9 today's deposition.</p> <p>10 Q Did Dr. Hopkins ever tell you that he was</p> <p>11 of the opinion, and expressed it to Johnson and</p> <p>12 Johnson in written form, that tremolite in any form</p> <p>13 should not be allowed in cosmetic talc products?</p> <p>14 A I have not discussed that with Dr.</p> <p>15 Hopkins.</p> <p>16 Q 357 is a December 21, 1995 memo from</p> <p>17 John Hopkins entitled CTPA talc monograph. Do you</p> <p>18 know what the CTPA was?</p> <p>19 A I think it is a toiletry fragrance group</p> <p>20 in Britain, but I'm not positive.</p> <p>21 Q It is the British counterpart to the CTFA</p> <p>22 in the United States, correct?</p> <p>23 A I don't know. I'm not familiar with them</p> <p>24 as an organization.</p> <p>25 Q You mentioned Dr. Pooley. There's a</p>	<p>1 detected by x-ray diffraction, that batch of talc is</p> <p>2 unacceptable for cosmetic use, whether or not</p> <p>3 subsequent examination by optical or electron</p> <p>4 microscopy shows the contaminant is not fibrous."</p> <p>5 Were you aware that was being discussed at Johnson</p> <p>6 and Johnson?</p> <p>7 A This isn't Johnson and Johnson. This is</p> <p>8 the industry group in Britain. So they are just</p> <p>9 saying take the first step of the J41 and no need to</p> <p>10 do the second step.</p> <p>11 Q What they are basically saying is once you</p> <p>12 are find tremolite, that's it. Don't use it.</p> <p>13 That's what Dr. Hopkins says.</p> <p>14 A That is not what this says. This says</p> <p>15 unacceptable for cosmetic use. And the reason they</p> <p>16 are doing this is to make sure that it is a cheap,</p> <p>17 basically quick way to do it. But you are going to</p> <p>18 throw a lot of material out potentially without any</p> <p>19 hazard to humans.</p> <p>20 Q Whether or not subsequent examination by</p> <p>21 optical or electron microscope shows the</p> <p>22 contamination is not fibrous. That is what he says,</p> <p>23 correct?</p> <p>24 A That is correct.</p> <p>25 Q What does he say about whether Johnson and</p>

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<p>1 Johnson should be using this CTFA method in Great 2 Britain?</p> <p>3 A I haven't seen this document before, so I 4 haven't reviewed it. I don't know what he said.</p> <p>5 Q Go to Bates number 77498. Do you see 6 where I blew it up, he talks about the detection 7 limits for the J41 method and he says, "You should 8 use another method called the step scanning method." 9 Correct? What he states is you should use a method 10 beyond the J41 method, and he states the increased 11 sensitivity is critical for better detection of 12 amphiboles, which otherwise using XRD procedures 13 alone would go undetected. Members urged strongly 14 to use this increased sensitivity, if at all 15 possible, particularly in light of the various new 16 foreign talcs that are emerging in the marketplace." 17 Correct?</p> <p>18 A I don't see exactly where you pointed to.</p> <p>19 Q Right where I have the -- I even pulled a 20 lateral for you.</p> <p>21 A I see that.</p> <p>22 Q So in Great Britain Dr. Hopkins was saying 23 use something more sensitive than the XRD. Did you 24 ever recommend to the FDA, and did you ever let the 25 FDA know that internally you were using a method in</p>	<p>1 This is a 1995 document. I would 2 have to review it to really understand what the 3 context for this was.</p> <p>4 Q Let me show you a document from 2001 5 marked Exhibit 361, identified as a memo from Rich 6 Zazenski to Donna Dennis, subject talc 7 specification. Luzenac, this is a Luzenac business 8 record. Am I correct that Luzenac was one of your 9 suppliers of talc?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Luzenac was the predecessor, I think, of 12 Imerys.</p> <p>13 Q They were a part of the trade association 14 that you were a member of, the CTFA?</p> <p>15 A Yes.</p> <p>16 Q They were part of the group that made 17 recommendations as to what testing methods should be 18 used to the FDA?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Whoever the supplier was at that time was 21 participating.</p> <p>22 Q Do you see where they state, "Additionally 23 we can discuss an asbestos specification option 24 which required that cosmetic talc does not contain 25 detectable asbestos when analyzed by a transmission</p>
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<p>1 Great Britain that you were not recommending to the 2 FDA?</p> <p>3 A I'll go back and say we have always used 4 transmission electron microscopy, in addition to the 5 J41.</p> <p>6 So with regard to the sensitivity of 7 Johnson and Johnson's methods, we are very confident 8 with the sensitivity, even more sensitive than what 9 Dr. Hopkins notes here.</p> <p>10 I have not reviewed this document 11 before. I've not discussed it with Dr. Hopkins, so 12 I really don't know the context in which this was 13 discussed.</p> <p>14 Q In Great Britain Johnson and Johnson was 15 recommending an XRD procedure that was more 16 sensitive than the one that they were recommending 17 to the FDA, correct?</p> <p>18 A Again, I haven't had the opportunity to 19 discuss this with Dr. Hopkins. I had not seen this 20 before today.</p> <p>21 As we were talking about FDA 22 communications between Johnson and Johnson and FDA 23 regarding asbestos testing, and the J41 was a method 24 that was developed in the early '70s, based upon 25 what was practical and reliable at the time.</p>	<p>1 electron microscopy TEM. I think we all recognize 2 XRD, PCM and PLM are simply not sensitive enough to 3 provide complete assurance that talc is free of 4 detectable asbestos." Do you see that?</p> <p>5 A Yes, I do.</p> <p>6 Q Johnson and Johnson was aware of that, 7 correct?</p> <p>8 MR. SMITH: Objection.</p> <p>9 Q That "the XRD, PCM and PLM methods are 10 simply not sensitive enough to provide complete 11 assurance that talc is free of detectable asbestos."</p> <p>12 MR. SMITH: Objection.</p> <p>13 A If you look at the method, the J41 and the 14 sensitivity of that method, and it is covered in 15 that 1986 response to the citizen petition, it is 16 more sensitive, it can pick up asbestos even more 17 sensitive than what is in the environment.</p> <p>18 In other words, if you find any 19 asbestos using those methods, it is more likely to 20 come from the air than it is from that sample.</p> <p>21 So I see what it is saying about 22 increased sensitivity using different methodologies, 23 and that's why the would be important for me to 24 speak to Dr. Hopkins to understand the context. 25 What are they looking for there, when you have an</p>

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<p>1 environmental level that's many, many times higher 2 than what your sensitivity is you that are striving 3 for. It is a strange line of discussion, so I think 4 the context is critical.</p> <p>5 Q What was my question Ma'am?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A Did I know there was more sensitivity than 8 what was currently being used to pick up asbestos.</p> <p>9 Q No. That's not what I asked. I move to 10 strike your entire statement, Ma'am. Please answer 11 this question. This is the question I'm asking 12 you.</p> <p>13 Was Johnson and Johnson aware that 14 the XRD and the PLM method are not sensitive enough 15 to provide complete assurance that talc is free of 16 detectable asbestos? Was Johnson and Johnson aware 17 of that?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I'm going to disagree that is it a correct 20 statement based on what I've seen in the 1986 FDA 21 response to the citizens petition. So why would you 22 get more sensitive testing than would be -- more 23 sensitive than what's in the environment?</p> <p>24 That's the part that doesn't make 25 sense.</p>	<p>1 We don't need a more sensitive method 2 based on that analysis. That is why I would like to 3 talk to Dr. Hopkins and understand the context for 4 this discussion.</p> <p>5 Q So you are not able to testify here today 6 without having another conversation with Dr. 7 Hopkins. Is that what you are saying?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A I have provided you with the document I'm 10 making reference to.</p> <p>11 Q I'm going to get to that, I promise you.</p> <p>12 MR. SMITH: Don't talk over the 13 witness.</p> <p>14 Q I promise you. I'm asking you, Ma'am, do 15 you need to speak to Dr. Hopkins again before I talk 16 to you more about this document?</p> <p>17 MR. SMITH: Were you finished with 18 your last answer?</p> <p>19 A I don't recall.</p> <p>20 MR. SMITH: Can you read back where 21 she was in her last answer before opposing counsel 22 talked over her.</p> <p>23 MR. PLACITELLA: I'm going to 24 withdraw that question and ask you this question.</p> <p>25 Q Ma'am, in order to answer any more</p>
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<p>1 Q You do not agree with this statement?</p> <p>2 A The method may be -- there may be a more 3 sensitive method, but if the ambient air and the 4 water and everything, there's more asbestos in the 5 environment than you are trying to find here with a 6 testing method. It doesn't make sense to me.</p> <p>7 That's what I'm saying.</p> <p>8 Q Ma'am, respectfully again, I move to 9 strike your testimony. You testified in the 10 beginning of this deposition that you are not a 11 geologist and you are not an expert in asbestos 12 testing.</p> <p>13 All I'm asking you, Johnson and 14 Johnson, is whether you agreed that the SRD and PLM 15 are not sensitive enough to give complete assurance 16 that talc is free of detectable asbestos. If you 17 don't agree, say it. If you do agree, say it. We 18 don't need a speech.</p> <p>19 MR. SMITH: Objection, ignore those 20 comments.</p> <p>21 A I appreciate that you don't like my answer 22 because we don't need a more sensitive method and 23 that's covered very specifically in that 1986 24 response to the citizens petition that I made 25 reference to earlier.</p>	<p>1 questions about detection methods, do you need to 2 speak with Dr. Hopkins? That is all I'm asking.</p> <p>3 A No.</p> <p>4 Q Can we agree that Johnson and Johnson and 5 the CTFA understood that the J41 method was not 6 sensitive enough for testing for chrysotile 7 asbestos?</p> <p>8 MR. SMITH: Objection.</p> <p>9 Q Can we agree to that?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A No.</p> <p>12 Q 266. I'm going to show you what's been 13 marked October 31, 1972 on Johnson and Johnson 14 letterhead.</p> <p>15 MR. SMITH: I think you misspoke.</p> <p>16 Q October 31, 1972?</p> <p>17 MR. SMITH: This document has been 18 marked Exhibit 266.</p> <p>19 MR. PLACITELLA: You are correct.</p> <p>20 MR. SMITH: It is a letter.</p> <p>21 MR. PLACITELLA: You are correct.</p> <p>22 266.</p> <p>23 Q The subject is analysis of Johnson's Baby 24 Powder for chrysotile asbestos. Do you see that?</p> <p>25 A Yes.</p>

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<p>1 Q It talks about using the X-ray diffraction 2 method, correct? 3 A Yes. 4 Q What Johnson and Johnson says is that 5 method has been demonstrated that it was possible to 6 detect chrysotile and talc at a level of 2 to 3 7 percent by weight, correct? 8 MR. SMITH: Objection. 9 A Yes. 10 Q Am I correct that the FDA wanted to 11 regulate chrysotile asbestos, but Johnson and 12 Johnson took the position that was no reason to do 13 so because there was never no evidence ever that 14 there was asbestos chrysotile in Johnson's talc? 15 MR. SMITH: Objection. 16 A That's correct, because chrysotile is an 17 industrial asbestos. It is not found with talc in 18 the cosmetic mines. 19 Q So what Johnson and Johnson told the FDA 20 was there's no reason for you to regulate it 21 because there was no chrysotile ever found in any 22 mine that was the source of Johnson's Baby Powder, 23 correct? 24 MR. SMITH: Objection. 25 A Chrysotile is an environmental issue. So</p>	<p>1 when they were working out this industry standard 2 for asbestos testing. 3 Q You know that what Johnson and Johnson 4 ultimately did was try to discourage the FDA from 5 using that method, right? 6 A I'm not aware of that. 7 Q You are not aware as you sit here today 8 that Johnson and Johnson's own experts recommended 9 to them repeatedly that the pre-concentration method 10 be been used by Johnson and Johnson? 11 A No. I'm not aware of that. 12 MR. SMITH: Objection. 13 Q You have in front of you a memo from 14 February 26, 1973 to Mr. Ashton at Johnson and 15 Johnson from the Colorado School of mines. Do you 16 see that? 17 A Yes. 18 Q Have you ever seen this document before? 19 A I don't specifically recall that I have. 20 Q The Colorado School of Mines is one of the 21 entities that you relied upon when you were 22 communicating with the FDA concerning the testing of 23 asbestos in baby powder, correct? 24 A Yes. 25 Q Do you see at the top it talks about</p>
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<p>1 it is an EPA regulated material. So that's correct, 2 it should not be regulated by the FDA. 3 Q I know from reading your prior testimony 4 you have been asked questions about the methodology 5 that Johnson and Johnson considered called the 6 pre-concentration method. Do you know what I'm 7 talking about? 8 A Yes. 9 Q And do you understand that at one point in 10 time the FDA was considering using the 11 pre-concentration method for testing for asbestos in 12 talc, correct? 13 A Correct. 14 Q And that NIOSH actually recognized the 15 viability of that methodology, correct. You knew 16 that? 17 A No, I wasn't aware of that. And Johnson 18 and Johnson's own experts recommended that it adopt 19 or use the pre-concentration method for determining 20 whether there was asbestos in Johnson and Johnson 21 talc, correct? 22 MR. SMITH: Objection. 23 A I don't know that, but I do know that 24 Johnson and Johnson offered to explore the 25 concentration method with the group during the '70s</p>	<p>1 sample grounded talc ore separated using a 2 centrifuge? I colored it so you can see. 3 A Yes. 4 Q That's a pre-concentration method, 5 correct? 6 A I don't know that is specifically the 7 pre-concentration method. It is a concentration 8 method, yes. 9 Q And when they did that, if you go to the 10 page that references February 26, 1973, according to 11 this document when that method was used, the 12 Colorado School of Mines found tremolite and 13 actinolite. Do you see that? 14 A Yes. 15 Q Do you see where it says relative to 16 possible asbestos type minerals the above table 17 shows that samples 3071S contained slight traces of 18 tremolite, actinolite minerals. Sample 3271S 19 suspected to contain very minor amount of 20 serpentine, which may be chrysotile? Do you see 21 that? 22 A I do. 23 Q Is this the first time you learned that 24 the Colorado School of Mines was using the 25 centrifuge method and found tremolite asbestos and</p>

<p style="text-align: right;">Page 142</p> <p>1 chrysotile in their testing?</p> <p>2 A I'm looking at this document and I don't</p> <p>3 think this has anything to do with cosmetic testing</p> <p>4 of talc. So the fact that they use a concentration</p> <p>5 method is completely unrelated to cosmetic testing.</p> <p>6 And I know that if you look at the</p> <p>7 table on page 8087 you can see at one where 41.6</p> <p>8 percent weight of major magnesite -- it is just the</p> <p>9 members here do not look like cosmetic talc. I</p> <p>10 don't know what they were testing and why they were</p> <p>11 using that method.</p> <p>12 Q But you are not an expert in the testing</p> <p>13 methods, right?</p> <p>14 A I understand the general methodology, but</p> <p>15 I'm not an -- I'm looking at this and telling you</p> <p>16 this isn't cosmetic testing.</p> <p>17 Q Well, that wasn't the point of my</p> <p>18 question. My question was whether this methodology</p> <p>19 was recommended for the testing of asbestos by</p> <p>20 Colorado School of Mines to Johnson and Johnson, and</p> <p>21 that was the focus of my question.</p> <p>22 A The answer to your question is no, because</p> <p>23 this has nothing to do with cosmetic testing.</p> <p>24 Q Well, let's go to 263. 263 is a report</p> <p>25 from the Colorado School of Mines, and the title is,</p>	<p style="text-align: right;">Page 144</p> <p>1 method when you have to find something like a needle</p> <p>2 in a haystack, correct?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A They are not specifically saying this is a</p> <p>5 a pre-concentration method, but they use a radiant</p> <p>6 separation method and again, nothing in here that I</p> <p>7 could see, although this is the first time I've seen</p> <p>8 this, has anything about cosmetic testing and new</p> <p>9 standards.</p> <p>10 Q You don't think this is about the</p> <p>11 pre-concentration method?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A The pre-concentration method, that's a</p> <p>14 very specific method.</p> <p>15 Q Can you go to where it says objective?</p> <p>16 "The objective of the work was to develop a</p> <p>17 procedure to screen for the talc for the presence of</p> <p>18 chrysotile and tremolite and actinolite asbestos</p> <p>19 minerals. Based on past experience with detecting</p> <p>20 and identifying minerals when present at low levels</p> <p>21 a concentration of the phases could be detected, was</p> <p>22 considered essential to the success of any suggested</p> <p>23 the procedure." Do you see that?</p> <p>24 A I do.</p> <p>25 MR. PLACITELLA: Let's take a break</p>
<p style="text-align: right;">Page 143</p> <p>1 A Procedure to Examine Talc for the Presence of</p> <p>2 Chrysotile and Tremolite, Actinolite Fibers, Johnson</p> <p>3 and Johnson. Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Go to the introduction. It says the</p> <p>6 purpose of this document is to report the methods</p> <p>7 used at Colorado School of Mines Institute for the</p> <p>8 detection of chrysotile and/or tremolite actinolite</p> <p>9 in samples predominantly composed of talc. Do you</p> <p>10 see there?</p> <p>11 A Yes.</p> <p>12 Q It goes on to say, "As the impurity level</p> <p>13 becomes very low, less than one percent, it is</p> <p>14 necessary to examine increasingly larger amounts of</p> <p>15 sample in order to detect the impurity. As a result</p> <p>16 of requirement to detect the proverbial needle in a</p> <p>17 haystack, we have evolved a procedure which</p> <p>18 pre-concentrates the impurities prior to</p> <p>19 examination." Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And what they did is they again used a</p> <p>22 centrifuge, correct?</p> <p>23 A Yes.</p> <p>24 Q And that was a method that was discussed</p> <p>25 with Johnson and Johnson, the pre-concentration</p>	<p style="text-align: right;">Page 145</p> <p>1 now.</p> <p>2 THE VIDEOGRAPHER: The time is</p> <p>3 approximately 2:11. We are going off the record.</p> <p>4 (Recess taken)</p> <p>5</p> <p>6 THE VIDEOGRAPHER: We are back on the</p> <p>7 record. The time is approximately 2:23 p.m.</p> <p>8 BY MR. PLACITELLA:</p> <p>9 Q Okay. Before you had referenced a couple</p> <p>10 of times Dr. Pooley. Do you remember that?</p> <p>11 A Yes.</p> <p>12 Q You are aware, or can we agree, that Dr.</p> <p>13 Pooley also recommended to Johnson and Johnson they</p> <p>14 use of the pre-concentration method when using X-ray</p> <p>15 diffraction?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A No, I'm not aware of that.</p> <p>18 Q You are not aware of that?</p> <p>19 A No.</p> <p>20 Q 45 is a memo from May 16, 1973 on Johnson</p> <p>21 and Johnson letterhead. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q I assume you have seen this before?</p> <p>24 A I don't believe I have.</p> <p>25 Q Do you know who T.H. Shelley is?</p>

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<p>1 A No.</p> <p>2 Q Who is Dr. A.J. Goudie?</p> <p>3 A I don't know.</p> <p>4 Q Do you see where it says Dr. T. Shelley is</p> <p>5 going to go to England on May 25th?</p> <p>6 A Yes.</p> <p>7 Q That is where Dr. Pooley was, correct?</p> <p>8 A Yes.</p> <p>9 Q And it says that "England is considering</p> <p>10 method of pre-concentrating the asbestos so as to be</p> <p>11 able to analyze by x-ray." Do you recall see that?</p> <p>12 A Yes.</p> <p>13 Q It says, "They find no asbestos by doing</p> <p>14 this with Italian talc." Do you see that?</p> <p>15 A Yes.</p> <p>16 Q It says they find Pooley, Dr. Pooley,</p> <p>17 right?</p> <p>18 A Yes.</p> <p>19 Q Point zero five percent of a tremolite in</p> <p>20 Vermont, correct?</p> <p>21 A I see that, yes.</p> <p>22 Q Is this the first time you learned that</p> <p>23 Dr. Pooley used a pre-concentration method on</p> <p>24 Vermont talc and found tremolite?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 in the research and development group.</p> <p>2 Q It says, "The British Toiletry Preparation</p> <p>3 Federation is in the process of drafting</p> <p>4 specifications on talc. These will involve density</p> <p>5 concentration techniques followed by x-ray analysis.</p> <p>6 Fred Pooley has developed the methods and checked</p> <p>7 the Italian talc for chrysotile and other asbestos</p> <p>8 contaminants. He found none. However, I'm</p> <p>9 concerned that our Vermont talc will from time to</p> <p>10 time show traces of tremolite." Do you see that?</p> <p>11 A I do.</p> <p>12 Q Have you ever seen this before?</p> <p>13 A No. Tremolite is not asbestos.</p> <p>14 Q My question is have you ever seen this</p> <p>15 document before?</p> <p>16 A Yes, I understand.</p> <p>17 Q Did you know before today that Dr. Pooley</p> <p>18 was involved in putting specifications together for</p> <p>19 Great Britain that recommended the concentration</p> <p>20 technique for testing?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A I was not, and I have not seen the full</p> <p>23 recommendation on the specification.</p> <p>24 Q Today is the first time you learned that</p> <p>25 Dr. Pooley was working on the concentration method</p>
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<p>1 A We know that there can be tremolite in</p> <p>2 association with talc. It doesn't say asbestos. So</p> <p>3 that's news.</p> <p>4 Pre-concentration method, is not</p> <p>5 recommending -- this in 1973. The J41 was developed</p> <p>6 and published in '76. How he used it and when he</p> <p>7 used it and why he used, it is not immediately</p> <p>8 apparent on this sheet.</p> <p>9 Q But it say he used a pre-concentration</p> <p>10 method and the .05 percent and when they were talking</p> <p>11 about -- let's just read it. "England is</p> <p>12 considering method of pre-concentrating the asbestos</p> <p>13 so as to be able to analyze by x-ray." Correct?</p> <p>14 A Yes.</p> <p>15 Q And they find no asbestos, in quotes, by</p> <p>16 doing this with the Italian talc. They find, that</p> <p>17 is Pooley, .05 percent of a tremolite type in</p> <p>18 Vermont." Correct?</p> <p>19 A Yes.</p> <p>20 Q Now, 46 is the follow up memo dated June</p> <p>21 4, 1973. The re: is talc. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q It states, it is to Dr. Robert F. Rolle.</p> <p>24 Do you know who that is?</p> <p>25 A He was in Johnson and Johnson, I believe,</p>	<p>1 in Great Britain and that was found in the Johnson</p> <p>2 and Johnson documents, the first time you knew that?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A It is not the first time I knew that.</p> <p>5 Johnson and Johnson knew about the concentration</p> <p>6 method, was willing to discuss it with the FDA, so</p> <p>7 this is not -- I was not aware Pooley specifically</p> <p>8 had been working on it for the British Toiletry</p> <p>9 Association. That was your question. The answer</p> <p>10 was no.</p> <p>11 Q 47. Did you know that Dr. Pooley ran the</p> <p>12 concentration method on Vermont talc and found</p> <p>13 actinolite?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A No.</p> <p>16 Q You have in front of you a June 6, 1973</p> <p>17 memo on Johnson and Johnson stationery. I blew up</p> <p>18 the right portion. It says, it talks about the note</p> <p>19 from June 4th. Do you remember that, we just went</p> <p>20 through it?</p> <p>21 A Yes.</p> <p>22 Q It says, "Note the concentration</p> <p>23 techniques in the drafted specification for analysis</p> <p>24 of asbestos." Do you see that?</p> <p>25 A Yes.</p>

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<p>1 Q Then it goes on and says, "Shelley reports 2 that Pooley had found actinolite in our Vermont talc 3 by his concentrating technique." Do you see that? 4 A I do. Actinolite is not asbestos. 5 Q All I asked you was, do you see that. 6 A I do see it. 7 Q Okay. Is today the first time you learned 8 that Pooley found actinolite in the Vermont talc 9 using the concentration method? 10 MR. SMITH: Objection. 11 A Yes, but actinolite is not asbestos. 12 Q Ma'am, I'm asking you a simple question. 13 Is today the first time you learned that Pooley 14 found actinolite in Vermont talc using the 15 concentration method? 16 A Yes, and actinolite is not asbestos. 17 Q Ma'am, did I ask you whether your opinion 18 was whether it was asbestos or not? What can you 19 tell me? Tell me everything you know about 20 actinolite. 21 A We can go to the 1986 -- 22 Q No, Ma'am. I want to know everything you 23 know about actinolite. I don't want you to refer to 24 anything. Tell me everything you know about 25 actinolite.</p>	<p>1 mention actinolite, the complication I hear and how 2 you ask the question, that is asbestos, which it is 3 not. The clarification is important. 4 Q Ma'am, move to strike your testimony, with 5 all due respect. My question to you is tell me 6 everything that you, Dr. Nicholson, know from your 7 own mind, without reference to any documents about 8 actinolite. Tell me everything you know. 9 MR. SMITH: Objection. 10 A Extremely rare asbestos. 11 Q And based on what reference, besides the 12 1986 report that you are talking about? 13 A The 1986 report contains multiple 14 documents. One of them is a document called The 15 Misclassification of Asbestos. An excellent 16 reference that talks about all of the 1970s and of 17 the confusion and misrepresentation of various 18 finding by different microscopic techniques. It is 19 an excellent reference that clarifies many of the 20 things that you are pointing out today. 21 Q My question was what? 22 MR. SMITH: Objection. 23 Q What was my question? 24 A Repeat your question. 25 Q Do you have any idea what my question was?</p>
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<p>1 MR. SMITH: Let me say that you can't 2 do that. 3 MR. PLACITELLA: Yes, I can do that, 4 and I will call the judge. 5 MR. SMITH: You can't -- 6 MR. PLACITELLA: I will call the 7 judge. 8 MR. SMITH: If you want to call the 9 judge, call the judge. You can't in the middle of 10 an answer just talk over the witness. 11 MR. PLACITELLA: I can when the 12 witness will not answer the question, Counsel. 13 MR. SMITH: The witness - 14 Q I'll withdraw the last question and the 15 ask the question again. Tell me everything you know 16 from your own knowledge without reference to any 17 documents, everything you know about actinolite? 18 A Because the specificity of words are 19 critical here, and very easy to confuse individuals, 20 whether they know this area or not, with language. 21 Using documents and referring to tables and decision 22 treatises, very nicely outlined in the 1986 FDA had 23 response to the citizens petition, is the right way 24 to review this subject, not shooting from hip. 25 So when you mention tremolite, you</p>	<p>1 A Well, sometimes I don't, but if you repeat 2 it I will. 3 Q Because you are going to wind up and say 4 whatever you are going to say regardless of my 5 question, right? 6 MR. SMITH: Objection. 7 A Incorrect. 8 Q Ma'am, can an honest and forthright 9 witness provide a simple answer to a simple 10 question? 11 A If it is asked clearly, yes, I can. 12 MR. SMITH: Excuse me. If we are 13 going to go down this trail, we are going to stop. 14 MR. PLACITELLA: You can stop at any 15 time you want. We will go to the judge. We will 16 let her read the transcript and she will decide 17 whether the witness is being responsive. If you 18 want to stop the deposition, stop the deposition, 19 otherwise I'm asking my questions. 20 MR. SMITH: You can't insult people. 21 MR. PLACITELLA: No one is being 22 insulted. 23 MR. SMITH: She is being insulted. 24 MR. PLACITELLA: No she isn't. 25 MR. SMITH: Yes, she is. You can't</p>

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<p>1 do that.</p> <p>2 MR. PLACITELLA: No, she isn't.</p> <p>3 MR. SMITH: You can't do that. You</p> <p>4 can't cut witnesses off in the middle of an answer.</p> <p>5 You have got to stop that. If you want to keep it</p> <p>6 up, if you are saying you have a right to do that</p> <p>7 and you have a right to make insulting comments,</p> <p>8 then we will stop and we will give the transcript to</p> <p>9 the judge.</p> <p>10 MR. PLACITELLA: You know what, you</p> <p>11 stop the transcript any time you need to do it.</p> <p>12 MR. SMITH: I'm asking you to stop</p> <p>13 insulting the witness.</p> <p>14 MR. PLACITELLA: I'm not insulting</p> <p>15 the witness.</p> <p>16 MR. SMITH: Stop cutting her off in</p> <p>17 the middle of an answer. That's all I'm asking you</p> <p>18 to do. Ask her a question, she answers it and if</p> <p>19 you think she is not responsive, you move to strike.</p> <p>20 You don't insult her. You don't talk over her.</p> <p>21 MR. PLACITELLA: Are you done with</p> <p>22 your speech?</p> <p>23 MR. SMITH: But I'm asking you to</p> <p>24 just behave like that.</p> <p>25 MR. PLACITELLA: I'm asking you to</p>	<p>1 over her.</p> <p>2 Q Ma'am, do you agree with me that an honest</p> <p>3 and forthright witness can provide a simple answer</p> <p>4 to a simple question?</p> <p>5 MR. SMITH: Objection. I'm</p> <p>6 instructing you not to answer. That question is</p> <p>7 just to harass her and we are not doing that.</p> <p>8 Q Ma'am, did Dr. Pooley find actinolite</p> <p>9 using the pre-concentration method in Vermont talc?</p> <p>10 MR. SMITH: Objection.</p> <p>11 Q Yes or no?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q Yes or no? Can you not answer my question</p> <p>14 yes or no, Ma'am? Why don't we ask that question</p> <p>15 first. Answer my question, yes or no, did Dr. Pooley</p> <p>16 find actinolite using the pre-concentration method</p> <p>17 in Vermont talc? Can you answer that question, yes</p> <p>18 or no?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Yes, but he did not specify whether or not</p> <p>21 it was asbestiform or not.</p> <p>22 Q I just asked you whether you could answer</p> <p>23 it yes or no. I didn't ask you anything more. Are</p> <p>24 you able to answer my question yes or no, whether</p> <p>25 Dr. Pooley found actinolite in Vermont talc using</p>
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<p>1 just let me ask my questions, and if the witness</p> <p>2 will respond to the questions, we will get through</p> <p>3 the deposition.</p> <p>4 MR. SMITH: The witness is responding</p> <p>5 to the questions.</p> <p>6 Q Ma'am --</p> <p>7 MR. SMITH: If she wants to refer to</p> <p>8 a document, she is allowed to do that.</p> <p>9 MR. PLACITELLA: She can when you ask</p> <p>10 her questions. If I don't refer her to a document,</p> <p>11 then she can't.</p> <p>12 MR. SMITH: She's here as a corporate</p> <p>13 representative. She brought these documents to help</p> <p>14 refresh her recollection.</p> <p>15 MR. PLACITELLA: This is not form</p> <p>16 objection. You are way out of bounds here.</p> <p>17 MR. SMITH: No, you are out of</p> <p>18 bounds.</p> <p>19 MR. PLACITELLA: You are way out of</p> <p>20 bounds. I'm asking you not to do it.</p> <p>21 MR. SMITH: I'm happy to take this</p> <p>22 transcript to the judge, if that is what you want</p> <p>23 want to do.</p> <p>24 MR. PLACITELLA: Let's keep going.</p> <p>25 MR. SMITH: Not if you keep talking</p>	<p>1 the pre-concentration method?</p> <p>2 MR. SMITH: Objection.</p> <p>3 Q Can you answer that question yes or no?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I cannot answer it without misleading the</p> <p>6 jury.</p> <p>7 Q Did you rely upon Dartmouth College as one</p> <p>8 of the authorities for your submissions to the FDA</p> <p>9 on the issue of asbestos and Johnson's Baby Powder?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Yes.</p> <p>12 Q Are you aware that Dartmouth College used</p> <p>13 and recommended the concentration method when</p> <p>14 testing Johnson's talc?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I would have to go back and look at the</p> <p>17 exact documents to review their methods.</p> <p>18 Q The question is are you aware, as you sit</p> <p>19 here today, whether they did that or not?</p> <p>20 A I would have to go back and look at the</p> <p>21 documents to verify the testing methods.</p> <p>22 Q As you sit here today, you don't know</p> <p>23 whether Dartmouth College ever used the</p> <p>24 concentration method in assessing whether there was</p> <p>25 asbestos in Vermont talc?</p>

<p style="text-align: right;">Page 158</p> <p>1 MR. SMITH: Objection.</p> <p>2 A I prefer to refer to the actual report to</p> <p>3 be sure of what I'm answering, so I'll not answer</p> <p>4 until I've had a chance to look at it.</p> <p>5 Q Find any document you want. Go ahead and</p> <p>6 look.</p> <p>7 A They did use centrifugation. Just on a</p> <p>8 quick glance I can't tell if all of their testing</p> <p>9 used centrifugation or not.</p> <p>10 Q Did any of their testing find -- do you</p> <p>11 know whether any of the Dartmouth College testing</p> <p>12 ever found actinolite in the Vermont talc?</p> <p>13 A Based on the conclusion I see here, I</p> <p>14 don't see actinolite mentioned, but I do see no</p> <p>15 amphibole or garnet or asbestos impurities were</p> <p>16 observed.</p> <p>17 Q In terms of the information that was</p> <p>18 conveyed by Johnson and Johnson concerning the tests</p> <p>19 that were done by Dartmouth College, the FDA was</p> <p>20 never told one way or the other whether actinolite</p> <p>21 or they found no actinolite. What is the answer?</p> <p>22 A I'm looking at the conclusions and I don't</p> <p>23 see any reference to actinolite.</p> <p>24 Q Does it say no amphiboles were found,</p> <p>25 regardless of whether they are asbestiform?</p>	<p style="text-align: right;">Page 160</p> <p>1 using the concentration technique because it brings</p> <p>2 amphiboles into a reasonable concentration range and</p> <p>3 it says that is mandatory?</p> <p>4 A Yes, but it is important to look before</p> <p>5 that. There's a whole discussion about how you can't</p> <p>6 tell -- you could do grain counts, but you can't see</p> <p>7 the specificity of the grain whether or not it is an</p> <p>8 amphibole without concentrating.</p> <p>9 Q I'm fine with that. It says the reasons</p> <p>10 stated, as you just stated, a concentration</p> <p>11 technique is mandatory because it brings the</p> <p>12 amphiboles into a reasonable concentration range for</p> <p>13 optical and other methods of analysis, correct?</p> <p>14 A That is what it says.</p> <p>15 Q And if you go to page 6 where it says</p> <p>16 results, and now they are testing for asbestiform</p> <p>17 minerals. Do you recall that? It says, "Two gram</p> <p>18 samples of ore and ore spiked with actinolite</p> <p>19 were separated and analyzed as described above." Do</p> <p>20 you see that?</p> <p>21 A Yes.</p> <p>22 Q Then it talks about results are in table</p> <p>23 2. It says table 3 shows concentrations of heavy</p> <p>24 fractions, mostly carbonite and actinolite and talc</p> <p>25 ore and talc product. Do you see that?</p>
<p style="text-align: right;">Page 159</p> <p>1 A Yes.</p> <p>2 Q I'll show you J and J 58. Did you provide</p> <p>3 J and J 58 to the FDA at any point in time?</p> <p>4 A That document I was just looking is dated</p> <p>5 June 28, 1971. I see numerous documents from March</p> <p>6 of 1974, but I don't see that specific document.</p> <p>7 Q This document is entitled, from Dartmouth</p> <p>8 College, Confidential, by the way, Analysis of Talc</p> <p>9 Products and Ores for Asbestiform Amphiboles. Do you</p> <p>10 see that?</p> <p>11 A Yes.</p> <p>12 Q And Dartmouth College is one of the</p> <p>13 experts that you relied upon in your submissions to</p> <p>14 the FDA, correct?</p> <p>15 A At least in 1971, yes.</p> <p>16 Q And again in 1976?</p> <p>17 A Perhaps. I would have to go through this</p> <p>18 and see.</p> <p>19 Q In this document dated March 1974, it</p> <p>20 states, "The purpose of the study is to develop</p> <p>21 methods for measuring the concentration of</p> <p>22 asbestiform amphiboles in fine grain talc products.</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q You see on the second page it talks about</p>	<p style="text-align: right;">Page 161</p> <p>1 A Yes.</p> <p>2 Q So you see that here they are actually</p> <p>3 using the concentration method and recommending it</p> <p>4 in order to determine whether amphiboles are in the</p> <p>5 Vermont product, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A What I've seen, and again I'm not an</p> <p>8 expert in all the methodology from just what you</p> <p>9 have shown me, is that they needed it for this</p> <p>10 specific methodology.</p> <p>11 I don't know that you can universally</p> <p>12 say you have to use the concentration method with</p> <p>13 this optical microscopic technique. That's what</p> <p>14 they are saying.</p> <p>15 Q What they are saying to Johnson and</p> <p>16 Johnson is that it is mandatory. Isn't that their</p> <p>17 words?</p> <p>18 A You can't take that out of context though.</p> <p>19 It is mandatory when using the optical microscopic</p> <p>20 technique they are using, not for every method</p> <p>21 available.</p> <p>22 Q It talks about on page 7 when they use</p> <p>23 the concentration method, they found ore samples</p> <p>24 contain 2300 parts per million actinolite and the</p> <p>25 talc product contains 170 parts per million</p>

<p style="text-align: right;">Page 162</p> <p>1 actinolite. Actinolite is the dominant fiber form 2 amphibole in the ore and talc product provided by 3 Windsor Minerals. Small amounts of anthophyllite 4 might be present. 5 That is what they wrote, correct? 6 A I see that. I'll say that that does not 7 mean it is asbestos. 8 Q Ma'am, I'm just asking if that's what they 9 wrote. 10 A Yes, I understand. I don't want the 11 answer to be misleading. 12 Q When up told the FDA that there was no 13 amphibole of any sort ever found in a Johnson and 14 Johnson talc product, you did not include this 15 report, correct? 16 A I didn't see the report here, so I can't 17 say that we had sent it for sure. And I don't know 18 what the sample was that they tested, so I would 19 have to go back and verify that to answer your 20 question definitively. 21 Q You never even saw this report until as 22 you are sitting here right now, right? 23 A Well, I've looked at a lot of reports and 24 they are kind of technical. So you have to really 25 look at them very carefully. I don't recall this</p>	<p style="text-align: right;">Page 164</p> <p>1 concentrate. The method is straightforward and 2 rapid requiring about 20 minutes of operator time 3 and about one hour overall. If removal of 4 carbonates is desired, these times may become 30 5 minutes to two hours respectively." Do you have see 6 that? 7 A Yes. 8 Q To be fair to you, you had never seen this 9 before today, correct? 10 A No, but I can -- I see it now and I've 11 read through it. 12 Q We are going to be back here again, so 13 I'll ask you more questions when you have some 14 time to digest. 15 A I don't need time. I can see what it 16 means. 17 Q Am I correct that internally, as a follow 18 up to this, Johnson and Johnson actually 19 acknowledged that the concentration method was the 20 best method? 21 MR. SMITH: Objection. 22 A I doubt that because this basically says 23 it is a very difficult method and hard to quantify. 24 It sounds like it is extremely difficult to 25 execute.</p>
<p style="text-align: right;">Page 163</p> <p>1 one specifically, but again, I have not dug through 2 again to see if this matches up to the one I have. 3 Q And it is not in that book in front of you 4 of test results given to the FDA, correct? 5 A I didn't see it there. 6 Q 352. Are you aware that after Johnson and 7 Johnson got this report they actually discussed it 8 internally and verified the method? 9 A No, I was not aware of. 10 Q You have in front you 3-11-74, March 11, 11 1974 memo on Johnson and Johnson letterhead. The 12 subject, method of concentration of asbestos in 13 talc. Do you see that? 14 A Yes. 15 Q It talks about the procedure used by Dr. 16 Reynolds from Dartmouth, correct? 17 A Yes. 18 Q What you write internally is, "The 19 procedure for heavy fibers actinolite and tremolite 20 permit the detection of asbestos at original 21 concentration as low as .02 percent by weight while 22 the existing procedures, step scanning, X-ray 23 diffraction, are effective to .02 percent. The 24 dispersion staining technique of optical microscopy 25 was employed to detect tremolite fibers in the</p>	<p style="text-align: right;">Page 165</p> <p>1 Q Johnson and Johnson, after having 2 discussions about the concentration method with Dr. 3 Pooley, Dartmouth University and Colorado School of 4 Mines, after having all those discussions, fought 5 against the FDA using that method, didn't 6 they? 7 MR. SMITH: Objection. 8 A I don't think we fought against anybody. 9 Q Did you actually conclude, Johnson and 10 Johnson, that adoption of a pre-concentration method 11 by the FDA would be disturbing and troublesome for 12 Johnson and Johnson? 13 A Well, based on the documents you just gave 14 me, I would not be surprised if that was a 15 recommendation, but it sounds like it is very 16 difficult to do, hard to repeat, technically 17 intense, so probably not the kind of thing that most 18 individuals could execute. 19 Q Ma'am, I'm asking you whether internally 20 you, Johnson and Johnson, determined that you were 21 going to oppose adopting the pre-concentration 22 method by the FDA because it was disturbing and 23 troublesome to Johnson and Johnson? 24 MR. SMITH: Objection. 25 A I don't think it would be disturbing and</p>

<p style="text-align: right;">Page 166</p> <p>1 troublesome to Johnson and Johnson. As I just said, 2 it sounds like it is a very difficult method to 3 execute. 4 Q 471 is a memo from Mr. Ashton dated 5 November 24, 1976. Do you see that? Have you ever 6 seen this document before? 7 A I don't believe I have. 8 Q Here it says, Mr. Ashton, by the way, was 9 known inside of Johnson and Johnson as Mr. Talc, 10 correct? 11 A I don't know. 12 Q Do you see where it says Mr. Ashton writes 13 to George Lee, "Attached is a copy of a disturbing 14 proposal request which the FDA has currently made 15 available to qualified bidders. The scope of the 16 work is the separation of asbestos and food, drugs 17 and talc for Identification and determination." Do 18 you see that? 19 A Yes. 20 Q 369. And Johnson and Johnson, actually 21 after hearing recommendations from their own 22 experts, came to the conclusion that using the 23 concentration method was not in the interest of 24 Johnson and Johnson, correct? 25 MR. SMITH: Objection.</p>	<p style="text-align: right;">Page 168</p> <p>1 would not be in the worldwide company interest to do 2 this, correct? 3 MR. SMITH: Objection. 4 A Yes. 5 Q And what you ultimately determined was 6 that you wanted to avoid using this technique at all 7 costs and keep it quiet, right? 8 MR. SMITH: Objection. 9 A No. 10 Q 353. I'm going to show you what's been 11 marked February 28, 1975, on Johnson and Johnson 12 letterhead. Subject, review of CTFA methodology for 13 the detection of asbestos in talc as well as 14 comments on PPF methodology. Do you see that? 15 A Yes. 16 Q It goes through here the methodology that 17 Johnson and Johnson wants adopted, correct? 18 A This looks like a proposed methodology. 19 Q And how Johnson and Johnson concludes the 20 memo is, "We really want to exclude concentration 21 techniques in any proposed analytical procedure and 22 are really looking at this method very quietly. So 23 that we will be well informed and up to date with 24 this technology. We want to avoid promotion of 25 this approach." Did you ever see that before?</p>
<p style="text-align: right;">Page 167</p> <p>1 A Are you looking at this document that you 2 just gave me? 3 Q No, I'm asking a different question. 4 A Can you please repeat that? 5 Q Yes, Ma'am. After getting advice from 6 your experts about the viability of the 7 concentration method and its usefulness. Johnson 8 and Johnson came to the conclusion that the adoption 9 would not be in the interest of Johnson and Johnson 10 worldwide, correct? 11 MR. SMITH: Objection. 12 A I don't know what you are looking at, but 13 I would accept that's true because of the other 14 documents you have gave me that is a technically 15 difficult method to execute. 16 Q You have in front of you 369? 17 A Yes. 18 Q This is a memo from 1975, again, on 19 Johnson and Johnson letterhead? 20 A Yes. 21 Q And it talks about Dr. Pooley again and 22 his recommendations? Correct? 23 A Yes, I see that. 24 Q And what you say is we deliberately have 25 not included a concentration technique as we felt it</p>	<p style="text-align: right;">Page 169</p> <p>1 MR. SMITH: Objection. 2 A I have not, but I've seen in documents 3 noting that discussions where Johnson and Johnson 4 has said we will be happy to discuss this method. 5 Q This document says you want to avoid the 6 promotion of this approach, doesn't it, when it 7 talks about your methodologies? 8 MR. SMITH: Objection. 9 Q That's what it says. 10 Q That's what it says, but it doesn't mean 11 we were trying to suppress it. It means we weren't 12 promoting it. 13 Q You didn't want it adopted. 14 A You showed me documents just a minute ago 15 that showed it was technically intense and difficult 16 to execute. 17 Q You say you wanted to keep this very 18 quiet. That is what the document says, right? 19 MR. SMITH: Objection. 20 A So, my experience dealing with the FDA, 21 especially when there are multiple other companies, 22 if you raise an issue, everybody starts talking 23 about it and it can be real conversations. 24 We did say very explicitly to the 25 FDA, if you would like to discuss it we would be</p>

<p style="text-align: right;">Page 170</p> <p>1 happy to talk to you about it. We were not 2 oppressing it, but we didn't think it was a good 3 methodology, and you just showed me a document that 4 says it was technically difficult to perform. So it 5 wouldn't be in a standard methodology that others 6 perhaps could not get and repeat consistently. 7 Q But your experts did it multiple times 8 over, didn't they? 9 MR. SMITH: Objection. 10 A They are experts. 11 Q That is the point, Ma'am, isn't it? 12 Experts in the testing could use the methodology and 13 in fact your experts did and were successful in 14 using it, true? 15 MR. SMITH: Objection. 16 A In the discussion of the developments of 17 methodologies, correct. 18 Q But even though your expert used the 19 methodology and recommended it, it was your position 20 that you wanted to look at it very quietly and avoid 21 promotion, correct? 22 MR. SMITH: Objection. 23 Q That was your position, Johnson and 24 Johnson's position? 25 MR. SMITH: Objection.</p>	<p style="text-align: right;">Page 172</p> <p>1 MR. SMITH: Objection. 2 A I'll have to look at what you are 3 referring to. 4 Q Are you aware of that as you sit here 5 today? 6 A No, I'm not. Not in production material, 7 talcum powder. 8 Q So you are not, as you sit here, just so 9 we are clear, you are not aware of any test done for 10 Johnson and Johnson on Johnson's Baby Powder using 11 the concentration technique that found asbestos? 12 A No. 13 Q If you are not aware of it, you certainly 14 didn't provide it to the FDA. Is that fair? 15 A Yes. 16 Q I want to focus a little bit, at least get 17 some background on the Lewin report and the 18 exchanges with the FDA by Johnson and Johnson on the 19 Lewin report, okay? 20 A Yes. 21 Q Hopefully we won't get too much 22 controversy over this. 23 Is it your understanding that Dr. 24 Lewin tested a series of talc based products in the 25 early 1970s for the FDA? You are aware of that?</p>
<p style="text-align: right;">Page 171</p> <p>1 A So I'll say again. I'm reading this and I 2 see this, and based on the other information that we 3 have seen, it makes sense to me we would not want it 4 to it to become a prominent part of the discussion 5 because it is a technically difficult method to 6 execute, and when people who are not experts try to 7 reproduce it, even people in Johnson and Johnson's 8 labs, they were getting variable results. You 9 showed me that document a couple minutes ago. 10 MR. PLACITELLA: This is a good time 11 to take a break. 12 THE VIDEOGRAPHER: The time is 13 approximately 3:00 p.m. and we are going off the 14 record. 15 (Recess taken) 16 17 THE VIDEOGRAPHER: The time is 18 approximately 3:13 p.m. and we are back on the 19 record. 20 21 BY MR. PLACITELLA: 22 Q I assume that you are aware that Johnson 23 and Johnson hired experts to test Johnson's Baby 24 Powder that used the concentration technique and 25 found asbestos?</p>	<p style="text-align: right;">Page 173</p> <p>1 A Yes. 2 Q And you are aware that Dr. Lewin, 3 according to his analysis, found asbestos in some of 4 those products? 5 A Thought he found asbestos in some of those 6 products, yes. 7 Q Do you know if he issued a report -- let's 8 make sure we are on the same page, August 3, 1972. 9 You have seen that, correct? 10 A Yes. 11 Q I'll put it on the screen. August 3, 12 1972, a letter from Lewin to the FDA enclosing his 13 final analytical results, correct? 14 A Yes. 15 Q Is this report one of the results he had 16 was that in this analysis he found chrysotile 17 asbestos in Johnson's Baby Powder, correct? 18 A He thought he did. That's what he said, 19 later refuted. 20 Q Ma'am, I'm just asking you. I didn't what 21 ask you what he thought. I said in this analysis as 22 reported in this particular document, he found 23 asbestos in the Johnson's Baby Powder, correct? 24 MR. SMITH: Objection. Let me ask, 25 were you in the middle of your answer?</p>

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<p>1 A I'm okay.</p> <p>2 Q I'm not asking you whether he changed</p> <p>3 later on. We will get to that. I'm giving you every</p> <p>4 opportunity.</p> <p>5 I'm saying in this report, what he</p> <p>6 reported in his analysis was finding asbestos in the</p> <p>7 Johnson and Johnson product, correct?</p> <p>8 A He thinks he found asbestos. So that is</p> <p>9 what he said, but his methods were not sufficient to</p> <p>10 say that.</p> <p>11 Q In this report does it say anything about</p> <p>12 his methods not being efficient to say that?</p> <p>13 A He didn't know that at the time.</p> <p>14 Q All I'm asking you, please, is in this</p> <p>15 report what he reported in his analysis was that he</p> <p>16 found asbestos in Johnson Baby Powder, correct?</p> <p>17 A He reported he thought he found asbestos.</p> <p>18 That's correct.</p> <p>19 Q And after that report came down, Johnson</p> <p>20 and Johnson had conversations with the FDA about the</p> <p>21 report, correct?</p> <p>22 A Yes.</p> <p>23 Q And in those conversations the FDA</p> <p>24 promised Johnson and Johnson not to release the</p> <p>25 Lewin Report publically until Johnson and Johnson</p>	<p>1 Q Right about that time Johnson and Johnson</p> <p>2 found out that the FDA had hired a second contractor to</p> <p>3 test the talc products, that being Sperry-Rand, correct?</p> <p>4 A Where would I see that in this document?</p> <p>5 Q I'm asking whether you know that.</p> <p>6 A I know that multiple people tested the talc.</p> <p>7 Sperry-Rand, I don't remember the name specifically.</p> <p>8 Q I'm talking about who the FDA hired. Do</p> <p>9 you know that they hired Sperry-Rand to test the</p> <p>10 Johnson and Johnson talc?</p> <p>11 A I know they hired an outside group to do</p> <p>12 that. I don't remember the exact name, if it is</p> <p>13 Sperry-Rand or somebody else.</p> <p>14 Q Have you seen any of the reports by</p> <p>15 Sperry-Rand?</p> <p>16 A I've seen the reports of the FDA testing</p> <p>17 or their contracted testing of the Lewin samples, if</p> <p>18 that is what you are referring to.</p> <p>19 Q Sperry-Rand is -- I'm sorry. 29 is an</p> <p>20 August 24, 1972 memo entitled Talc Asbestos Shower</p> <p>21 to Shower Talc. Have you seen this before?</p> <p>22 A I don't recall this specific document.</p> <p>23 Q And apparently, and this document was not</p> <p>24 provided at any time to the FDA, correct?</p> <p>25 A Not that I recall specifically.</p>
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<p>1 had a chance to review it, fair?</p> <p>2 A Yes, that's correct.</p> <p>3 Q 347 in this report, in this particular</p> <p>4 letter dated August 29, 1972, Johnson and Johnson</p> <p>5 writes on the subject of talc in asbestos in Shower</p> <p>6 to Shower brand body powder, correct?</p> <p>7 A Yes.</p> <p>8 Q What is reported is that the author spoke</p> <p>9 with the FDA on two different occasions, correct?</p> <p>10 A Yes.</p> <p>11 Q And brought them up to speed on the</p> <p>12 findings of Professor Pooley, correct?</p> <p>13 A Yes.</p> <p>14 Q That no chrysotile was found in the</p> <p>15 Italian talc, correct?</p> <p>16 A Yes.</p> <p>17 Q Not reflected anywhere in here is the</p> <p>18 findings of Professor Pooley finding actinolite in</p> <p>19 the Vermont talc, correct?</p> <p>20 A That is correct.</p> <p>21 Q It goes on to say that Dr. Schaffner at the</p> <p>22 FDA agreed not to release the Lewin Report until</p> <p>23 after Johnson and Johnson had a chance to go over</p> <p>24 it, fair?</p> <p>25 A Yes.</p>	<p>1 Q What this does, and we will go through it</p> <p>2 slowly, since you haven't seen it. It says, "Dr.</p> <p>3 Weisler, Director, Division of Cosmetics, FDA,</p> <p>4 called us this afternoon to report they had</p> <p>5 submitted a sample of Shower to Shower previously</p> <p>6 examined by Dr. Lewin to the Sperry-Rand scanning</p> <p>7 electronic microscopy this afternoon." Do you see</p> <p>8 that?</p> <p>9 A Yes.</p> <p>10 Q Does that refresh your memory?</p> <p>11 A Yes. I'm familiar with another master</p> <p>12 table that was not Sperry-Rand of retesting for the</p> <p>13 Lewin samples. That's why it took me a minute.</p> <p>14 Q Are you aware of this and did you</p> <p>15 investigate this conversation that Johnson and</p> <p>16 Johnson had with the Director at the FDA concerning</p> <p>17 the Sperry-Rand testing?</p> <p>18 A No, because I was looking at this January</p> <p>19 7, 1976 Lewin retest document.</p> <p>20 Q We are going to get there. I promise.</p> <p>21 Right now I'm focusing on the conversations that</p> <p>22 Johnson and Johnson had with the FDA concerning the</p> <p>23 Shower to Shower Sperry-Rand testing. Are you with</p> <p>24 me?</p> <p>25 A Yes.</p>

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<p>1 Q It states, "Report from Sperry-Rand was 2 that asbestos fibers could be detected in the 3 sample. Dr. Weisler said that he has in front of 4 him photographs of six fields at 12,000 X 5 magnification showing fibers with length to width 6 ratios of 10 to 1, to 50 to 1. One of them 7 appearing on the top talc plate." Do you see that? 8 A Yes. 9 Q It goes on to say that, "Johnson and 10 Johnson asked the FDA if Sperry-Rand handles 11 minerals, and the response was that they do a lot of 12 work with chrysotile." Correct? 13 A Yes. 14 Q The FDA further told Johnson and Johnson 15 that they believed that, "the man who did the work is 16 conservative and he would not have reported 17 chrysotile unless he was sure." Correct? 18 A Yes. 19 Q And Johnson and Johnson asked, "if he has 20 assured himself, that is the FDA, that the fibers 21 were not tremolite, which could be present in trace 22 amounts." And the response was, "He said the fibers 23 are characteristic of chrysotile and not tremolite." 24 Do you see that? 25 A Yes.</p>	<p>1 surprised again, because chrysotile would not be 2 found in talc. 3 Q Did I ask you that Ma'am, whether you were 4 surprised or not? Do you really want me to have a 5 judge read this and make a determination of whether 6 you are truly being responsive? 7 MR. SMITH: Objection. 8 Q Are we really going to do this? 9 MR. SMITH: Objection. Just ignore 10 those comments. 11 Q Are we really going to do this? 12 MR. SMITH: Please don't do that. 13 Please don't do that. It is not helpful. 14 Q Do you know anything about this conversation? 15 A Not until you showed it to me today. 16 Q It goes on to say that, "That information 17 is completely at variance with Johnson and Johnson's 18 information," correct? 19 A Specifically from McCrone, and we have a 20 letter here that says that 1971 through '76 McCrone 21 never found any asbestos in our talc material, so 22 yes, I'm well aware of that. 23 Q As you stand here as the witness for 24 Johnson and Johnson, let's be very clear. Are you 25 telling this jury that from 1971 to 1976 McCrone</p>
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<p>1 Q Do you have any knowledge of this conversation? 2 A I don't, but I'm not concerned because 3 chrysotile is an industrial asbestos fiber and not 4 found in talc material, so this speaks to me of 5 laboratory contamination. 6 Q Ma'am there's nothing in here about 7 laboratory contamination. I'm just asking if you 8 know anything about the conversation. 9 A I know what you are asking me, and I just 10 want to make sure you understand that chrysotile 11 does not occur in talc materials unless it is an 12 environmental contaminant. 13 Q Ma'am. did I ask you that question? 14 A No. But I thought it might be helpful to 15 your understanding. 16 Q I'm not asking you to help me with my 17 understanding. I'm asking you to answer questions 18 that are posed. 19 My question is, do you have any 20 information in your investigation about this 21 conversation that Johnson and Johnson had with the 22 FDA where the FDA related their contractor 23 found chrysotile asbestos in the Johnson and Johnson 24 products? That's all I'm asking. 25 A Not specifically, no, but I'm not</p>	<p>1 never found asbestos in any Johnson and Johnson talc 2 material? Is that what you are saying? 3 A Our production material, tested by McCrone, 4 did not have asbestos in it from 1971 to 1976. 5 Q I'm asking you Ma'am, are you telling this 6 jury, because it is important, that no test by 7 McCrone ever found asbestos from 1971 to 1976 in 8 Johnson and Johnson talc? Is that what you are saying? 9 MR. SMITH: Objection. 10 A There were two instances that were 11 referred to in that letter I mentioned that was 12 written in 1976 referring to 1971 to 1976. They 13 said in the last five years, and we have the letter 14 here that we can look at, and they did mention, I 15 believe, or maybe it was in a later letter, that 16 they had two instances of asbestos contamination 17 from external sources and they were able to verify 18 where those asbestos materials came from. 19 Q What was my question? 20 A You asked me if they never found any 21 asbestos, and there were some contaminant events. 22 I'm answering your question. 23 Q Your answer to the question is but for two 24 contamination events, McCrone never found any 25 evidence of asbestos when testing Johnson and</p>

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<p>1 Johnson talc. Is that what you are saying?</p> <p>2 A That is my understanding of talc cosmetic powders.</p> <p>3 Q Did McCrone ever find asbestos when testing</p> <p>4 the talc mine sources that were used for Johnson</p> <p>5 and Johnson cosmetic talc products?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A We would have to look at those reports.</p> <p>8 There are extensive surveys of the shafts that are</p> <p>9 used for cosmetic talc and they are complex</p> <p>10 documents that need to be looked at specifically to</p> <p>11 go through that.</p> <p>12 Q Ma'am, I'm just asking whether you know,</p> <p>13 as the representative of Johnson and Johnson,</p> <p>14 whether McCrone ever tested talc that was used in</p> <p>15 the Johnson and Johnson cosmetic talc products and</p> <p>16 found asbestos. That is my question.</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I think you have changed the question.</p> <p>19 Q That is my question. Can you answer that</p> <p>20 question?</p> <p>21 A Did McCrone ever find asbestos in cosmetic</p> <p>22 talc products. That was your question.</p> <p>23 Q No, Ma'am. My question was, did McCrone</p> <p>24 ever find asbestos in the talc that was used to</p> <p>25 manufacture -- I'll make it easier. I'll start over.</p>	<p>1 A I recall, and I have read documents,</p> <p>2 minutes from the meeting where the FDA came to</p> <p>3 Johnson and Johnson to discuss testing. I know</p> <p>4 there were other individuals there. I don't recall</p> <p>5 any conditions of who was going to speak, but I'm</p> <p>6 not surprised that there was a very specific agenda</p> <p>7 agreed to, if that's what you are referring to.</p> <p>8 Q Well, you know that before you had the</p> <p>9 meeting with other industry members, you had a</p> <p>10 private meeting with the FDA about the Lewin</p> <p>11 results, true?</p> <p>12 A Yes, and that is not unusual, if we are</p> <p>13 talking about our specific products.</p> <p>14 Q You, Johnson and Johnson, actually got an</p> <p>15 advanced copy of the Lewin Report before it was ever</p> <p>16 made available to any consumers or doctors or</p> <p>17 members of Congress, correct?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A Yes.</p> <p>20 Q When you met with the FDA, you assured the</p> <p>21 FDA that you gave them your entire background file</p> <p>22 on asbestos talc testing as it related to your</p> <p>23 cosmetic talc products, correct?</p> <p>24 A I don't know that specifically. I would</p> <p>25 have to go back and look at those documents to see</p>
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<p>1 Did McCrone ever find asbestos in</p> <p>2 any form in the source of the talc that was used for</p> <p>3 Johnson's cosmetic talc products?</p> <p>4 A They never found asbestos in the material</p> <p>5 that was used to make Johnson's Baby Powder.</p> <p>6 Q And that is what you told the FDA, you,</p> <p>7 Johnson and Johnson, correct?</p> <p>8 A That's correct.</p> <p>9 Q And you have actually met with the FDA and</p> <p>10 told them, in reviewing the Lewin reports, that</p> <p>11 there was never even a trace of chrysotile asbestos</p> <p>12 found in any Johnson and Johnson cosmetic talc</p> <p>13 product, true?</p> <p>14 A True.</p> <p>15 MR. SMITH: Objection.</p> <p>16 Q At some point you sat down with the FDA</p> <p>17 and actually discussed that issue about the Lewin</p> <p>18 results, correct?</p> <p>19 A Yes.</p> <p>20 Q And what you arranged at Johnson and</p> <p>21 Johnson was a private meeting with the FDA that you</p> <p>22 would have with the officials at the FDA and then</p> <p>23 you could agree with the FDA who would be allowed to</p> <p>24 speak at the meeting involving people other than</p> <p>25 Johnson and Johnson, correct?</p>	<p>1 what exactly was given.</p> <p>2 Q Exhibit 40 is a December 13, 1972 memo</p> <p>3 that discusses the meeting that you had with the FDA</p> <p>4 on November 1, 1972, correct?</p> <p>5 A Yes.</p> <p>6 Q What you indicated is that you pointed out</p> <p>7 and provided information and ordered your complete</p> <p>8 background files concerning talc and asbestos, correct?</p> <p>9 A Yes.</p> <p>10 Q Did you actually provide the FDA with your</p> <p>11 complete background files?</p> <p>12 A In November 29, 1972, we sent a number of</p> <p>13 documents. These are reports of retained samples</p> <p>14 from two lots that were examined by multiple</p> <p>15 different organizations.</p> <p>16 Q At that point in time did you provide the</p> <p>17 FDA with all of the asbestos testing evidence you</p> <p>18 had related to your cosmetic talc products?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A What I show here is we sent a number of</p> <p>21 different reports, testing of certainly lots.</p> <p>22 That's what I show that we sent to the FDA.</p> <p>23 Q That wasn't my question.</p> <p>24 MR. PLACITELLA: Are you able to read</p> <p>25 my question back.</p>

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<p>1 (The above question is read.)</p> <p>2 MR. SMITH: Note my objection.</p> <p>3 A So, I as I said, November 29, 1972, as</p> <p>4 pointed out in this December 13th memo, I pointed out</p> <p>5 providing information, offered our complete</p> <p>6 background files. Not all the tests have</p> <p>7 backgrounds files, to the administration prior to</p> <p>8 public disclosure, et cetera, and I have that here.</p> <p>9 It was provided to you in binder P-3.</p> <p>10 Q Can you identify the letter that you are</p> <p>11 referring to by date?</p> <p>12 A Tab C, November 29, 1972 letter.</p> <p>13 Q So on November 29, 1972, it is your</p> <p>14 testimony here under oath that Johnson and Johnson</p> <p>15 provided the FDA with all the testing evidence that</p> <p>16 it had related to whether there was asbestos in</p> <p>17 Johnson and Johnson cosmetic talc products, correct?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A As I corrected you before, not all of the</p> <p>20 testing information, complete background files.</p> <p>21 This is one, two, three, four, five different sets</p> <p>22 of documents around testing, and it refers to two</p> <p>23 specific lots.</p> <p>24 So you are saying all of the</p> <p>25 extensive testing. I don't know if there's other</p>	<p>1 A I don't know.</p> <p>2 Q And ultimately was a letter generated from</p> <p>3 the FDA summarizing the information and a product of</p> <p>4 what your discussions were and the input you provided?</p> <p>5 A From FDA?</p> <p>6 Q Yes, Ma'am.</p> <p>7 A There was a letter from the FDA.</p> <p>8 Q I'll show you what's been marked Exhibit</p> <p>9 50. 50 is a July 31, 1973 memo, a letter from the</p> <p>10 FDA talking about a summary and comments on</p> <p>11 Professor Lewin's analytical results for asbestos,</p> <p>12 correct?</p> <p>13 A Yes.</p> <p>14 Q You have seen that before?</p> <p>15 A Yes.</p> <p>16 Q That was part and parcel of the product of</p> <p>17 the discussion and submissions that you had given to</p> <p>18 the FDA on this subject, true?</p> <p>19 A This is from the FDA, not from us.</p> <p>20 Q No, we are talking this was the product</p> <p>21 of, in part, of the discussions you had with the</p> <p>22 FDA and the submissions you gave them.</p> <p>23 A That's correct.</p> <p>24 Q And in fact, the FDA notes on the second</p> <p>25 page of the document that you dispute the findings</p>
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<p>1 testing that would fall under the umbrella you are</p> <p>2 putting up. This is what was sent to the FDA and it</p> <p>3 is comprehensive related to these two lots.</p> <p>4 Q So everything you sent to the FDA is in</p> <p>5 that binder?</p> <p>6 A That is correct.</p> <p>7 Q In your meeting you express your concern</p> <p>8 to the FDA about the Lewin results, correct?</p> <p>9 A Yes.</p> <p>10 Q And you actually got the FDA official to</p> <p>11 agree not to release the Lewin results. I think he</p> <p>12 actually said, "Over my dead body will I release</p> <p>13 them." Is that right?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Yes, he did say that.</p> <p>16 Q At that point in time was your former</p> <p>17 executive working at the FDA?</p> <p>18 A I'm sorry?</p> <p>19 Q Your former executive who worked on talc,</p> <p>20 was he working at the FDA at that point in</p> <p>21 time?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A I don't know which executive you are</p> <p>24 referring to.</p> <p>25 Q Dr. Eiermann. Yes or no?</p>	<p>1 of Lewin using your own analysis and that no</p> <p>2 chrysotile was found, right?</p> <p>3 A Yes.</p> <p>4 Q 38. So we are all on the same page, I</p> <p>5 think this is what you referenced. I'm going to</p> <p>6 give you what's been marked J and J 38, and J and J</p> <p>7 38 is your letter to the FDA enclosing various</p> <p>8 expert testing results, correct?</p> <p>9 A Yes.</p> <p>10 Q And those included reports from McCrone,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q They included reports from Dr. Brown at</p> <p>14 Princeton?</p> <p>15 A Yes.</p> <p>16 Q Correct? They included reports from the</p> <p>17 Colorado School of Mines?</p> <p>18 A Yes.</p> <p>19 Q Your notes that have been marked as P-2, I</p> <p>20 don't really see anything in your notes related to,</p> <p>21 I'll call it the Lewin related testing, correct?</p> <p>22 A All in the binders here.</p> <p>23 Q I'm asking whether it is in your notes.</p> <p>24 A Not that I remember. Something about the</p> <p>25 1971 EPA State of New York symposia that it leads to</p>

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<p>1 Lewin testing.</p> <p>2 Q What do you know about that?</p> <p>3 A Just what I wrote down.</p> <p>4 Q That's all you know?</p> <p>5 A No. There was a 1971 meeting and the</p> <p>6 issue of asbestos testing and talc came up. Dr.</p> <p>7 Lewin was hired by FDA to do some testing and that</p> <p>8 led to the test results we have been discussing.</p> <p>9 Q I'm looking at your notes, on the second</p> <p>10 page it talks about, it says on page 2, "Reuters</p> <p>11 article lays out the theme." What does that mean?</p> <p>12 A There was a recent Reuters article written</p> <p>13 about talc, Johnson and Johnson and talcum powder,</p> <p>14 and some of the legal activities.</p> <p>15 Q That's something you read in preparation</p> <p>16 for today's deposition?</p> <p>17 A I did. I reread it.</p> <p>18 Q And then it says pivot back to. What do</p> <p>19 you mean by pivot back to?</p> <p>20 A I would have to look at the notes there.</p> <p>21 This refers to the fact that when you are talking</p> <p>22 about testing, you could easily pick out one</p> <p>23 document and present that as if it told the whole</p> <p>24 story of what people understood about asbestos</p> <p>25 testing and talc, and that is not correct. That</p>	<p>1 and the response is pivot back to. We are not</p> <p>2 playing games with language.</p> <p>3 MR. SMITH: Objection.</p> <p>4 A We are talking about asbestos. That's</p> <p>5 what I mean.</p> <p>6 Q It says, "No documentation validated</p> <p>7 positive test for asbestos. Then that material was</p> <p>8 used. That's why we use standards." That is your</p> <p>9 response to the Reuters article?</p> <p>10 A As we have done here today, you can pick</p> <p>11 out a little note here and a note there and imply</p> <p>12 that reflects that Johnson and Johnson products are</p> <p>13 contaminated with asbestos.</p> <p>14 There's no evidence to show that we</p> <p>15 ever released product to market that contained</p> <p>16 asbestos. And that's just a fact, and the McCrone</p> <p>17 letters in 1986 and 1976 refer to many, many years</p> <p>18 of negative testing of production material of</p> <p>19 Johnson's Baby Powder and Shower to Shower.</p> <p>20 Q I'm just trying to understand your notes.</p> <p>21 A I think they are good notes. Thanks for</p> <p>22 bringing it up.</p> <p>23 Q I was curious why, in preparation for</p> <p>24 today's deposition, you were talking about pivoting</p> <p>25 from the Reuters article.</p>
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<p>1 there's years of discussion and scientific debate</p> <p>2 about what is the appropriate testing for talc. And</p> <p>3 what is the right methodology, and Lewin really</p> <p>4 opened that up. And you see that laid out over a</p> <p>5 number of years leading to the J41.</p> <p>6 And so pivot back to a framework that</p> <p>7 lays out the context in which these documents lie so</p> <p>8 that nobody is misled to something that may not be true.</p> <p>9 Q I want to make sure we are -- you say</p> <p>10 Reuters articles lays out the theme. Pivot back to.</p> <p>11 Then you say, "We are not playing</p> <p>12 games with language. Go to McCrone letters." What</p> <p>13 does that mean?</p> <p>14 A That means when you say Tremolite, that</p> <p>15 does not mean asbestos. When you say actinolite,</p> <p>16 that does not mean asbestos. You say amphibole,</p> <p>17 that does not mean asbestos.</p> <p>18 It is very easy to confuse individuals</p> <p>19 by using a lot of geologic, numerology, nameology,</p> <p>20 and so just in plain speak, asbestos is what asbestos</p> <p>21 is, and you have to understand that. It is a disease</p> <p>22 causing febrile formations that are of concern that</p> <p>23 we have to make sure are not in our products.</p> <p>24 That's the bottom line.</p> <p>25 Q But we are going to the Reuters article</p>	<p>1 Did you think I was going to ask you</p> <p>2 about the Reuters article?</p> <p>3 A No, but I think the Reuters article picked</p> <p>4 up on some flashy facts and to make a story, and</p> <p>5 those facts were taken out of context of the</p> <p>6 framework of what's been going on in the last 50</p> <p>7 years around understanding asbestos testing and</p> <p>8 talcum powder.</p> <p>9 Q Were there discussions inside of Johnson</p> <p>10 and Johnson that you were a party to that were in</p> <p>11 response to the Reuters article?</p> <p>12 A Many people have asked me about talc</p> <p>13 safety in light of the Reuters article.</p> <p>14 Q When you say many people, I'm talking</p> <p>15 about inside of Johnson and Johnson.</p> <p>16 A Yes.</p> <p>17 Q Did you have a conversation with the</p> <p>18 CEO about it?</p> <p>19 A No.</p> <p>20 Q Who did you speak to inside of Johnson and</p> <p>21 Johnson about the response to the Reuters article?</p> <p>22 A Well, many people in the company know that</p> <p>23 that I have been -- number one, I was essentially</p> <p>24 the chief safety officer for our consumer group for</p> <p>25 three years and did a lot of work on talc safety.</p>

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<p>1 So many individuals and regular 2 employees, including security guards, asked me what 3 I think, and I tell them. 4 Q What executives did you discuss the 5 Reuters article with? What Johnson and Johnson 6 executives? 7 A Outside of our legal team, only the 8 individuals that I mentioned earlier today. 9 Q That being, so we clear, we are not 10 talking about security guards? 11 A We are talking Lynn Szczepaniak, Bobbette 12 Williams. Individuals in our quality organization. 13 Don Hicks, who is responsible for tale safety for 14 many years. 15 Q Did you talk to any PR people? 16 MR. SMITH: Objection. 17 A I did talk to our communications people. 18 They were asking for my help and advice. 19 Q Who was that? 20 A Ernie Knewitz. 21 Q Ernie Knewitz works for Johnson and Johnson? 22 A Yes. 23 Q Were you involved in any way in shaping 24 the message that was put forth by Johnson and 25 Johnson in response to the Reuters article?</p>	<p>1 school, Gordon Brown, Professor Pooley and Johnson 2 and Johnson, correct? 3 A Yes. 4 Q Now, 265. 265 is a report on the Johnson 5 and Johnson's Baby Powder that Gordon Brown 6 provided you, correct? 7 A Yes. 8 Q And that was the report that you gave to 9 the FDA, correct? 10 A It looks to be, yes. 11 Q And the methodology that Gordon Brown used 12 in analyzing the baby powder was X-ray diffraction, 13 correct? 14 A Yes. 15 Q And he concluded that there was no 16 evidence of chrysotile or tremolite found using that 17 technique, correct? 18 A Yes. 19 Q But you, Johnson and Johnson, knew that 20 the X-ray diffraction was not going to find 21 chrysotile under 2 or 3 percent, correct? We went 22 through that. 23 A We did, but this is in 1972. So these are 24 early days in asbestos testing. 25 Q Yes, Ma'am. And you also knew that the</p>
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<p>1 MR. SMITH: Objection. 2 A No. They asked me to fact check. 3 Q Fact check what? 4 A References to scientific literature, how 5 things were discussed to make sure that the language 6 was appropriate and scientifically correct. 7 Q Who asked you to do that fact check? 8 A Ernie. 9 Q So we are clear, Ernie -- 10 A Knewitz. 11 Q And his job specifically was what? 12 A Communications. 13 Q Did Johnson and Johnson actually hire outside 14 consultants to help them with this public relations? 15 MR. SMITH: Objection. 16 A I wouldn't know that. 17 Q That was something we would have to ask 18 Ernie Knewitz? 19 A Correct. 20 Q Just so the record is clear, going back to 21 the Lewin scenario and what you gave to the FDA, up 22 on the screen is a November 29, 1972 submission, 23 correct? That is what you have in front of you? 24 A Yes. 25 Q And again, we have McCrone, Colorado</p>	<p>1 x-ray diffraction was not going to find low levels of 2 tremolite, correct? 3 A Yes. 4 Q 35 is an October 27, 1972 report to 5 Johnson and Johnson from the Colorado School of 6 Mines, correct? 7 A Yes. 8 Q And that, again, was the report you gave 9 to the FDA, correct? 10 A Yes. 11 Q Again, the Colorado School of Mines used 12 X-ray diffraction as the testing method at the 13 request of Johnson and Johnson. That's what it 14 says, right? 15 A No. X-ray diffraction step scanning, 16 which is a more sensitive X-ray diffraction. 17 Q That's what was used? 18 A Yes. 19 Q And based upon the x-ray diffraction test, 20 the Colorado School of Mines didn't find any 21 chrysotile asbestos, correct? 22 A They didn't find serpentine, so, yes, 23 chrysotile would fall into that category. 24 Q They did not use the preconcentration 25 method that they were recommending in performing</p>

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1 these tests, correct?

2 A Well, in a different context. They were
3 looking -- Lewin said there was 3 percent chrysotile
4 in there. So you would not need a concentration
5 method to detect that level of chrysotile.

6 Q You would need it if you wanted to go
7 lower than that.

8 A You would.

9 Q And they did not use the concentration
10 method in analyzing these samples, correct?

11 A Correct.

12 Q 461. Now, 461 is a subsequent submission
13 that Johnson and Johnson made to the FDA concerning
14 the Lewin samples. Is that fair?

15 A Yes.

16 Q Dated May 25, 1973?

17 A That is correct.

18 Q And that was by a Martin J. Borger (ph.) or
19 Burger?

20 A I don't know. However you say it is fine
21 with me.

22 Q What you used was X-ray diffraction,
23 correct?

24 A Yes.

25 Q And using X-ray diffraction, he didn't

C E R T I F I C A T E

I, MARC BRODY, Notary Public and
Certified Shorthand Reporter of the State
of New Jersey, do hereby certify that prior
to the commencement of the examination
the witness was duly sworn by me to
testify the truth, the whole truth and
nothing but the truth.

I DO FURTHER CERTIFY that the
foregoing is a true and accurate transcript
of the testimony as taken stenographically
by and before me at the time, place and on
the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither
a relative of nor employee nor attorney nor
counsel for any of the parties to this
action, and that I am neither a relative
nor employee of such attorney or counsel,
and that I am not financially interested in
the action.

Notary Public of the State of New Jersey

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1 find any chrysotile, fair?

2 A That is correct.

3 Q Or tremolite?

4 A Or any number of, they list a whole bunch
5 of things he didn't find.

6 Q And he did not also apply the
7 concentration method, correct?

8 A Right. Again, it would be unnecessary
9 since Lewin was suggesting 2 and 3 percent of
10 chrysotile.

11 Q But if you wanted to find out if there was
12 any asbestos in there, you would use the
13 concentration method. You were just trying to
14 disprove Dr. Lewin. Is that what was going on?

15 A Actually, that was what was going on
16 because his methods were flawed.

17 MR. PLACITELLA: It is 3:58. I have
18 other things, but I think this is a place to stop
19 since we are about to change subjects. So why don't
20 we end for today and consult our calendars.

21 MR. SMITH: Fine.

22 THE VIDEOGRAPHER: The time is
23 approximately 3:59 p.m. This concludes today's
24 portion of the deposition.

25 (The deposition is adjourned.)

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Exhibit 84

From: Musco, Nancy [CPCUS]
Sent: Wednesday, May 27, 2009 7:25 PM
To: Chase, David J. (Dr.) [CPCUS]; Martin, Katharine [CPCUS]; Telofski, Lorena [CPCUS]
Subject: FW: Q&A Baby Powder
Attachments: What are the risks of inhalation.doc

Sensitivity: Confidential

All,

Who provided the data from the American Association of Poison Control? This is the information that I spent last week collecting and was putting in table form along with the J&J data. Perhaps I misunderstood my assignment but this represents much duplicate effort.

Thanks,

Nancy

From: Chase, David J. (Dr.) [CPCUS]
Sent: Wednesday, May 27, 2009 1:32 PM
To: Telofski, Lorena [CPCUS]
Cc: Wajszczuk, Charles [CPCUS]; Martin, Katharine [CPCUS]; Musco, Nancy [CPCUS]
Subject: FW: Q&A Baby Powder
Sensitivity: Confidential

Lorena,

Do you know where we could find data of the type I mentioned in my item # 3 (2 e-mails down)? Complete reports would be good, but brief summaries of the reports or statements based on the reports used by the company in the past would probably be more useful acutely.

Thanks,

David

<<What are the risks of inhalation.doc>>

From: Wajszczuk, Charles [CPCUS]
Sent: Wednesday, May 27, 2009 1:16 PM
To: Chase, David J. (Dr.) [CPCUS]; Costabel-Farkas, Margit [CONDE]; Martin, Katharine [CPCUS]
Cc: Ries, Gerd [CONDE]; Giernoth, Judith [CONDE]; Kuijpers, Harold [CONDE]; Andresen, Edda [CONDE]
Subject: RE: Q&A Baby Powder
Sensitivity: Confidential

David and All,

I'll leave determination regarding questions 1 and 2 below to you all. The information referred to in #3 would be of value. For #4, I don't know if anything other than sales data for ALL talc baby powder would be of value. These are numbers for all talc, but I'm guessing (since the info is not available) that most exposures are to baby powder. Chances of having

21 years of sales in the USA might be hard to find. It might be worth stating that the cases with no outcome may represent inquiries, not exposures, but we don't have that info either.

Charlie

Charlie

From: Chase, David J. (Dr.) [CPCUS]
Sent: Wednesday, May 27, 2009 12:59 PM
To: Wajszczuk, Charles [CPCUS]; Costabel-Farkas, Margit [CONDE]; Martin, Katharine [CPCUS]
Cc: Ries, Gerd [CONDE]; Giernoth, Judith [CONDE]; Kuijpers, Harold [CONDE]; Andresen, Edda [CONDE]
Subject: RE: Q&A Baby Powder
Importance: High
Sensitivity: Confidential

This strikes me as being a fairly complete analysis. I took the liberty of making a few suggestions concerning wording.

I also have a few larger questions:

1. Will this document be reviewed by legal, for example, John O'Shaughnessy, who has had a great deal of experience with talc issues over the years?
2. Will it be reviewed by external PR advisors with experience in talc issues?

3. Should it include empirical information on levels of exposure (inhalation) known to be likely from normal use of the product according to instructions, and on the magnitude of those levels compared to amounts of exposure needed to induce cancer or other adverse effects in animal studies? I understand that such information is available and has been made available in previous talc PR cases.

4. Is there any comparison that could/should be made between the AAPCC data and the data reported by the poison centers in Germany, Austria, and Switzerland? If so, should that be included?

David

<< File: What are the risks of inhalation.doc >>

From: Wajszczuk, Charles [CPCUS]
Sent: Wednesday, May 27, 2009 8:17 AM
To: Costabel-Farkas, Margit [CONDE]; Chase, David J. (Dr.) [CPCUS]; Martin, Katharine [CPCUS]
Cc: Ries, Gerd [CONDE]; Giernoth, Judith [CONDE]; Kuijpers, Harold [CONDE]; Andresen, Edda [CONDE]
Subject: RE: Q&A Baby Powder

All, << File: What are the risks of inhalation.doc >> Please see the write up. I think it addresses most of the issues.

Charlie

From: Costabel-Farkas, Margit [CONDE]
Sent: Monday, May 25, 2009 8:57 AM

To: Wajszczuk, Charles [CPCUS]; Chase, David J. (Dr.) [CPCUS]; Martin, Katharine [CPCUS]
Cc: Ries, Gerd [CONDE]; Giernoth, Judith [CONDE]; Kuijpers, Harold [CONDE]; Andresen, Edda [CONDE]
Subject: RE: Q&A Baby Powder
Importance: High

Dear all,

please find attached the draft answers to the questions provided by B-M, prepared by Edda, Judith and me.

Charlie, David, Katharine, could you maybe add any info on consequences or treatment of powder inhalation (two parts highlighted in yellow)?

It would be great to have your input as soon as possible, in order to share the draft with B-M for a final review by tomorrow.

Many thanks and best regards,

Margit

<< File: Baby Powder Questions_QA draft May 22.doc >>

Margit Costabel-Farkas
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Tel. +49 (0)2137/936-2188

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From: Andresen, Edda [CONDE]
Sent: Freitag, 22. Mai 2009 12:00
To: Costabel-Farkas, Margit [CONDE]
Cc: Ries, Gerd [CONDE]
Subject: Q&A Baby Powder

Hallo Margit,

ich habe angefangen, die Antworten einzufügen. Kannst du die gesundheitlichen Risiken ausführen und über den Rest drüberschauen?
Viele Grüße

Edda

<< File: Baby Powder Questions_QA draft May 22.doc >>

JNJ TALC000319188

Metadata

Custodian	Martin, Katharine	ORIGINAL
DateCreated	04/03/2010 12:00 AM	ORIGINAL
DateMod	05/27/2009 12:00 AM	ORIGINAL
FileName	FW: Q&A Baby Powder	ORIGINAL
From	"Musco, Nancy [CPCUS] [/O=JNJ/OU=CPCUSSK/CN=RECIPIENTS/CN=NMUSCO]"	ORIGINAL
ProdVol	TALC_PROD_033	ORIGINAL
Subject	FW: Q&A Baby Powder	ORIGINAL
To	"Chase, David J. (Dr.) [CPCUS];Martin, Katharine [CPCUS];Telofski, Lorena [CPCUS]"	ORIGINAL

Exhibit 85

TALC

1. Chemical and Physical Data

1.1 Synonyms and trade names

CAS Registry No.: 14807-96-6

Chem. Abstr. Name: Talc

Synonyms¹: Soapstone; steatite; talcum

Trade names¹: Agalite; Asbestine; B9 Finntalc P40; B13; B13 (mineral); Beaver White 200; CP 10-40; CP 38-33; Crystalite CR 6002; Desertalc 57; Emtal 500; Emtal 549; Emtal 596; Emtal 599; Fibrene C 400; French Chalk; FW-XO; HSDB 830; IT Extra; LMR 100; Microneeca K1; Micro White 5000A; Microtalc IT Extra; Mistron; MP 25-38; MP 40-27; MP 45-26; MST; MT 12-50; Mussolinite; NCI-CO6018; Nyltal 200; Nyltal 400; Pk-C; Pk-N; Polytal 4641; Polytal 4725; Potstone; Snowgoose; Steawhite; Supreme; Supreme dense; Talcan PK-P; Talcron CP 44-31

1.2 Structure of typical mineral

Molecular formula: $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$

The original X-ray spectra of talc (Gruner, 1934; Hendricks, 1938) indicated that the mineral had a monoclinic structure. Later investigations (Rayner & Brown, 1966; Ross *et al.*, 1968) demonstrated that many if not all talcs are triclinic (Table 1). The basis of the talc structure is characterized by a hexagonal sheet arrangement of SiO_4 tetrahedral groups linked in a common plane. Each SiO_4 tetrahedron shares three planar oxygen atoms with its neighbouring tetrahedra; the fourth oxygen, the apex of the tetrahedron, is not shared. Two such sheets are orientated so that unshared apical oxygen atoms face each other. The sheets are bonded by magnesium atoms, which are coordinated by two oxygens and one hydroxyl group from each sheet, which form a brucite layer. This structural arrangement results in a double-sheet structure in which the valency demands of the constituent atoms are completely satisfied. Crystals of talc are made up of stacks of these double-sheet units held together by the weakest of chemical bonds — the Van der Waal's forces. As the individual sheets cannot be bonded together, they can be separated by slight forces, causing slippage of the individual sheets along a perfect cleavage direction in the basal plane (Rohl *et al.*, 1976; Pooley & Rowlands, 1977).

¹These synonyms and trade names cover talc, talc-containing materials and talc contaminated with other minerals as admixtures.

Table 1. Lattice parameters and crystallographic axes of talc

Lattice parameters (nm)			Crystallographic axes			System	Reference
a	b	c	α	β	γ		
0.526	0.910	1.881	90°00'	100°00'	90°00'	Monoclinic	Gruner (1934)
0.527	0.913	1.888	90°00'	100°15'	90°00'	Monoclinic	Hendricks (1938)
0.528	0.915	1.89	90°00'	100°15'	90°00'	Monoclinic	Roberts <i>et al.</i> (1974)
0.5255	0.9137	0.9448	90°46'	98°55'	90°00'	Triclinic	Ross <i>et al.</i> (1968)
0.5293	0.9179	0.9496	90°57'	98°91'	90°03'	Triclinic	Ross (1984)

1.3 Chemical and physical properties

From Roberts *et al.* (1974)

- (a) *Hardness*: 1 on Mohs' scale
- (b) *Density*: 2.58-2.83
- (c) *Cleavage*: (001) perfect
- (d) *Colour*: Pale-green to dark-green or greenish-grey; also white, silvery-white, grey, brownish; translucent; pearly, greasy or dull
- (e) *Description*: Commonly thin tabular crystals, up to 1 cm in width. Usually massive, fine-grained, compact; also as foliated or fibrous masses or in globular stellate groups

1.4 Technical products and impurities

The chemistry of talc shows little variation, indicating that only a limited substitution of ions takes place in the mineral lattice. When expressed in the standard oxide form, the ideal chemical composition is: 31.7% MgO, 63.5% SiO₂, 4.8% H₂O (Pooley & Rowlands, 1977). Small amounts of aluminium and titanium may substitute to some extent for silicon, and it is common to find iron, nickel, manganese or chromium substituting to some extent for magnesium. Iron and nickel substitute for magnesium in the greatest amounts (Pooley & Rowlands, 1977), and a talc with almost complete substitution of magnesium by iron, called minnesotaite, is abundant in the iron formations of Minnesota, USA (Deer *et al.*, 1971). One major talc deposit in the eastern USA contains substantial amounts of nickel — up to 0.2% (Rohl *et al.*, 1976). Nickel-substituted talcs are also associated with serpentine bodies, at up to 0.5% by weight (Pooley & Rowlands, 1977). Table 2 gives examples of the mineral composition of talcs (Deer *et al.*, 1971).

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Table 2. Bulk chemical analysis of talcs (%)^a

Component	Talc ^b								
	1	2	3	4	5	6	7	8	9
SiO ₂	62.61	62.67	62.47	62.16	60.06	60.02	60.88	61.07	51.29
TiO ₂	—	—	—	—	—	—	0.10	—	0.04
Al ₂ O ₃	—	0.38	0.47	0.88	1.60	1.88	1.98	2.42	0.61
Fe ₂ O ₃	—	0.68	—	—	—	—	0.83	1.49	2.00
FeO	2.46	0.65	0.79	1.41	1.74	1.51	—	—	33.66
MnO	0.01	—	0.00	—	—	—	—	—	0.12
MgO	30.22	29.95	31.76	30.86	30.83	30.39	31.18	29.13	6.26
CaO	—	1.35	0.00	—	0.40	1.00	0.14	0.75	0.00
Na ₂ O	—	—	—	—	—	—	—	—	0.08
K ₂ O	—	—	—	—	—	—	—	—	0.03
H ₂ O ⁺	4.72	5.05	4.70	4.92	5.02	5.37	4.98	4.82	5.54
H ₂ O ⁻	—	—	0.06	—	—	0.32	—	—	0.24

^aFrom Deer *et al.* (1971)

^b1, talc, altered periodotite, Muruhatten, northern Sweden; 2, talc, Shabrov, Urals, USSR; 3, talc, Murphy, North Carolina, USA; 4, light-green talc, Malangen, Norway; 5, green talc, altered serpentine, Parma district, Appenines, Italy; 6, black talc, with carbonaceous material derived from a bluish-grey rock, Parma, Appenines, Italy; 7, talc, Mount Fitton, South Australia; 8, talc, altered tremolite, Yellandu Warangal district, Hyderabad, India; 9, greenish-grey iron talc (minnesotaite), East Mesabi range, Minnesota, USA

Since talc is formed by alteration or metamorphosis of rocks, it is found associated with many types of minerals. Rohl *et al.* (1976) listed the following minerals as commonly occurring in talc deposits: calcite, dolomite, magnesite, tremolite, anthophyllite, antigorite, quartz, pyrophyllite, micas and chlorites. Chrysotile and lizardite were noted as 'uncommon' constituents. When mined, talc ore may contain several of the minerals noted in Table 3.

In one study of Vermont (USA) talc, the mined and milled ore contained 20-100% each of talc and magnesite, a small amount of chlorite (5-20%) and minor amounts (<5%) of dolomite, calcite, quartz, phlogopite and biotite (Boundy *et al.*, 1979). An analysis of samples of mined and milled talc from New York (USA) yielded the following concentrations of minerals: talc, 12-50%; tremolite, 30-55%; anthophyllite, 3-35%; serpentine, 1-8%; calcite, <1-4%; and quartz, <0.1-20% (Schepers & Durkan, 1955a). A more recent examination of talc from Texas (USA) showed the presence of fibrous tremolite and antigorite (Gamble *et al.*, 1982). Rohl *et al.* (1976) showed that some US talcum powders marketed prior to 1975 contained chlorite, phlogopite, calcite, dolomite, quartz, kaolin, tremolite, anthophyllite, chrysotile, pyrophyllite and rutile. One French talc (Luzenac 15MOO) has been reported to contain 90% talc, 8% chlorite, 1% dolomite and no asbestos fibre (Talc de Luzenac, 1982). An Italian talc (grade 00000) was reported to contain 92% talc, 3% chlorite, 1% carbonates and 0.5-1% quartz and no tremolite or chrysotile asbestos (Wagner *et al.*, 1977).

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Table 3. Minerals that occur commonly in talcs^a

Mineral group	Phase	Formula
Carbonates	Calcite	CaCO_3
	Dolomite	$\text{CaMg}(\text{CO}_3)_2$
	Magnesite	MgCO_3
Amphiboles	Tremolite ^b	$\text{Ca}_2\text{Mg}_5\text{Si}_8\text{O}_{22}(\text{OH})_2$
	Anthophyllite ^b	$(\text{FeMg})_7\text{Si}_8\text{O}_{22}(\text{OH})_2$
Serpentine	Antigorite	$\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4$
	Chrysotile (uncommon)	$\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4$
	Lizardite (uncommon)	$\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4$
Others	Quartz	SiO_2
	Mica, e.g., phlogopite	$\text{K}_2(\text{Mg},\text{Fe})_6[\text{Si}_6\text{Al}_2\text{O}_{20}](\text{OH})_4$
	Chlorite, e.g., penninite	$(\text{Mg},\text{Al},\text{Fe})_{12}[(\text{Si},\text{Al})_8\text{O}_{20}](\text{OH})_{16}$
	Pyrophyllite	$\text{Al}_4[\text{Si}_8\text{O}_{20}](\text{OH})_4$

^aFrom Rohl *et al.* (1976)^bOccurring as nonasbestiform and asbestiform varieties

Technical products of talc are sold in a multitude of grades, which have functional or physical characteristics especially suited for certain applications. Clifton (1985) outlined the following guidelines for talc specifications by end use:

Ceramics: Uniform chemical and physical properties are required. Manganese and iron are usually objectionable. For high frequency insulators, no more than 0.5% calcium oxide, 1.5% iron oxide and 4% aluminium oxide can be tolerated.

Paints: Impurities that grind to colours other than white are highly objectionable. To yield the desired smooth paint film, at least 98.5% must pass through a 325-mesh screen.

Roofing: A low-grade, off-colour, impure talc is acceptable.

Insecticides: Requirements are chemical inertness with respect to toxicants, satisfactory bulk density and low abrasive characteristics.

Rubber: Many synthetic rubbers include ground talc as fillers in compounding formulations.

Cosmetics and pharmaceuticals: Talc must be grit free, finely sized, chemically pure and pleasing in colour. For cosmetics, talc must have good dry-slip characteristics.

Paper: Requirements include chemical inertness, softness, freedom from grit, satisfactory ink acceptance, brightness and dispersibility in water.

2. Production, Use, Occurrence and Analysis

2.1 Production and use

(a) Production

Talc-containing rocks were first used in prehistoric times for utensils and ornaments (Roe & Olson, 1983); the term 'talc' was first applied to this mineral in 869 AD (Kužvart, 1984). The abundance of talc and the facility with which it can be mined, combined with its many desirable functional properties, have made it an important industrial mineral. Mining of talc for commercial purposes probably began several hundred years ago when talc blocks were used for building materials and cooking utensils (Clifton, 1985).

The world reserve base of talc and the related aluminium silicate, pyrophyllite, is estimated to be 1200 million tonnes (Clifton, 1985; Table 4).

Table 4. Worldwide reserve base of talc and pyrophyllite^a

Region	Million tonnes
Africa	18
North America	580
South America	18
Asia and Oceania	362
Europe	172

^aFrom Clifton (1985); talc and pyrophyllite are not distinguished.

The first talc-grinding mill in the USA began operation in about 1880, suggesting the first large-scale US production of ground talc products. US production for many years continued to include both ground talc products and carved items (Clifton, 1985). 'Soapstone' blocks were first produced in open-pit operations, and the vast majority of world talc mining operations continue to rely on open-cast mining methods. Notable exceptions are in Austria and Italy, where necessity or the prospect of high-grade talc in deeper deposits has made underground mining an economically viable operation (Clarke, 1979). Talc sold in blocks is generally removed using hand tools; talc for grinding is mined by drilling and blasting methods (Clifton, 1985).

Practices for refining talc ores vary widely. In some operations, such as those of one mine in France, talc is initially sorted by hand to supply cosmetic talcs of different colour and physical characteristics (Clarke, 1979). Since most uses of talc have not required highly pure products, beneficiation and sophisticated milling and other processing techniques have not been used before shipping. Early talc mills were used to process both talc and cereal grains, the final product in both cases being a coarse powder (Roe & Olson, 1983).

The latest technology in talc refining employs flotation separation, drying of the filtered powder cake, and sizing or further grinding before shipping (Roe & Olson, 1983; Clifton, 1985). Flotation techniques are especially prevalent in North American, Norwegian and Finnish operations (Sinha, 1982).

Talc is mined in over 40 countries and is used in numerous manufacturing industries in over 60 countries (Roe & Olson, 1983; Harben & Bates, 1984). Commercial talc production figures in 1950-1983 are listed by region in Table 5.

Table 5. Talc production by world region, 1950-1983 (1000 tonnes)^a

Region/ country	Important producers	Year						
		1950	1960	1970	1980	1981	1982	1983
Africa	Egypt, South Africa	8	9	14	14	11	18	10
Asia	China, Republic of Korea	7	181	354	1312	1280	1248	1290
Australia		9	16	48	160	75	143	150
Europe	France, Italy, Austria, Finland, Norway	344	553	820	1180	1153	1195	1140
India and Pakistan		25	95	161	379	380	348	292
Japan		12	50	138	148	120	106	85
North America	USA	475	585	891	1124	1218	1035	998
South America	Brazil, Argentina	13	50	118	380	376	354	371
USSR		—	250	380	490	500	510	510

^aFrom Colonial Geological Surveys (1957); Institute of Geological Sciences (1967, 1978); British Geological Survey (1985). Figures are given for 'talc', although sometimes figures were not provided separately for talc production and pyrophyllite production.

Although the largest producers of talc are typically net exporters, notably Australia, Austria, China, France and the USA, several import talc in large quantities as well. Japan is by far the most important world market for talc, importing over 615 200 tonnes in 1983. Canada, the Federal Republic of Germany, Mexico, the UK, the USA and the USSR account for most of the remainder of talc imports (British Geological Survey, 1985).

(b) Use

Talc is one of the most versatile inorganic substances available to industry (Roe & Olson, 1983). Since its uses are dependent on the mineral character of the refined ore, more than many other industrial minerals, talc ores are often referred to by physical type, and used according to their functional characteristics. Although use patterns vary substantially from region to region, four major applications may be highlighted.

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Ceramics

In the USA, 35%, and in Europe, nearly 10%, of native or imported talcs is used in ceramics (Anon., 1982; Clifton, 1985). Talc is especially useful in ceramics for its colour, fast-firing and low shrinkage properties. It has been used in floor- and wall-tiles, china, glazes, electrical porcelains, sanitary ware, kiln furniture and pottery (Clifton, 1985). Some china contains 15% talc by weight, while some pottery contains 40%. Up to 80% talc has been used in ceramic insulators (Roe & Olson, 1983).

Paper

The most important use of talc in Europe and Japan and the fastest-growing use in the USA is in the coating and filling of paper (Anon., 1982; Roe & Olson, 1983). The largest talc importer, Japan, uses 80% of its imports in the paper industry (Clarke, 1979). This statistic, combined with the 50% consumption pattern of talc for paper in Europe (Anon., 1982), makes this the predominant use of talc in the world (Clarke, 1979).

Plastics and building materials

In 1983, about 165 000 tonnes of talc were used in the plastics, rubber and roofing industries in the USA, representing 20% of the total consumption (Clifton, 1985). Talc has become an important component of many types of US plastics, as a stabilizer, reinforcer and filler used at up to 70% w/w. In roofing materials, talc is added at 10-35% to asphalt in composite shingling materials, to impart stability and weather resistance (Roe & Olson, 1983).

Paints

Approximately 15-25% of the talc used in most industrialized nations is as a pigment extender and filler in paints (Anon., 1982). As with the paper application, fineness of grade and colour are most important to the functional characteristics of the compound. US consumption of talc for use in paints was 213 000 tonnes in 1979 (Roe & Olson, 1983) and 150 000 tonnes in 1983 (Clifton, 1985).

Other uses

A significant, although less commercially important use of talc is in cosmetics. In the USA and Europe, approximately 5% of native and imported ores are used for this purpose (Anon., 1982; Clifton, 1985). Talc is directly available to consumers as facial cosmetics and talcum powders. US talcum powders marked prior to 1973 contained up to 95% by weight talc mineral; however, some commercial talcum powders contained no talc (e.g., starch was used). Mineral impurities such as amphibole minerals (tremolite, anthophyllite) and quartz were found in concentrations up to 14 and 35% by weight, respectively (Rohl *et al.*, 1976). Talc is also used as an excipient in pharmaceuticals and as a filler in toothpastes and soaps (Rohl & Langer, 1979; Kuřvart, 1984).

Other uses of talc are as a cereal grain polisher (especially rice), as an ingredient in floor waxes and shoe polishes, as a carrier and diluent for pesticides, as a textile component, as an oil absorber, as a lubricant and in spackling and patching compounds (Rohl & Langer, 1979; Roe & Olson, 1983; Clifton, 1985).

(c) *Regulatory status and guidelines*

Occupational exposure limits in various countries are listed in Table 6.

Table 6. Occupational exposure limits for talc (mg/m³)^a

Country	Year	Total dust (mg/m ³)	Respirable dust (mg/m ³)
Australia	1978	2.5	
Czechoslovakia	1976	6	
Finland	1981	5 ^b	
France	1985		2 ^b
Italy	1978	5	1.6
Norway	1981	6	
United Kingdom	1985	10	1
USA			
ACGIH	1986		2 ^b
OSHA	1983	(20 mppcf) ^{b,c}	
USSR	1976	4	
Yugoslavia	1971	12	4

^aFrom International Labour Office (1980); Direktoratet för Arbeidstilsynet (1981); Työsuojeluhallitus (1981); US Occupational Safety and Health Administration (OSHA) (1983); Health and Safety Executive (1985); Institut National de Recherche et de Sécurité (1985); American Conference of Governmental Industrial Hygienists (ACGIH) (1986)

^bAsbestos fibre standards are used for fibrous forms

^cContaining <1% quartz

2.2 Occurrence

(a) *Natural occurrence*

Talc rocks are formed by several complex geological processes reacting upon many chemically diverse preexisting rock types. Hydrothermal alteration of magnesia- and silica-rich ultramafic rocks, under a range of low-to-moderate temperatures and pressures, may produce talc. Thermal metamorphosis of silica-rich dolomite will also produce talc. These processes, however, also commonly result in the formation of a number of other coexisting mineral phases — predominantly hydrous magnesium silicates. Some of these — for example, anthophyllite, tremolite and serpentine minerals (including chrysotile) — may occur as microscopic intergrowths with talc, as macroscopic nodules, or even as discrete zones within or adjacent to talc. Talc rock is therefore often a mixture of minerals varying in kind and quantity (Rohl & Langer, 1974; Rohl *et al.*, 1976; Clifton, 1985).

Fibre intergrowths are often such that even extensive beneficiation may not yield a pure product. Thus, where fine-grained intergrowths of talc and tremolite occur, the processed product will probably contain residual tremolite (Rohl *et al.*, 1976).

(b) *Occupational exposure*

Talc-milling processes do not usually alter the mineral composition of the talc mixture delivered to the mill, but rather produce a talc with different physical properties dependent on particle size. Exposure to talc dust occurs during mining, crushing, separating, bagging, loading and in end-use facilities, such as rubber dusting and addition of talcs to ceramic clays and glazes. Since industrial talc is a mixture of various associated minerals, occupational exposure is to a mixture of mineral dusts.

Studies that provide information on occupational exposures to talc are summarized in Table 7 and described in more detail below. As with most industrial dust exposures, nearly all measurements made prior to approximately 1970 were done by collecting particles in an impinger and counting them by optical microscopy. Concentrations are thus expressed as millions of particles per cubic foot of air (mppcf).

In Georgia, USA, average dust exposures for miners using jackhammer drills were 1440 mppcf and those for millers 52 mppcf. The talc was reported to contain 45% tremolite and 45% talc, with little or no free silica (Dreessen, 1933). Average dust concentrations in a talc mine were reported to range from 32-855 mppcf (six samples), whereas average mill exposures ranged from 17-1672 mppcf (14 samples). The dust was reported to contain 70% talc, 20-30% dolomite and 10% tremolite, and no free silica except for occasional fragments; its morphology was described as 'bladed crystals'. Highest dust exposures were in bagging operations (Dreessen & DallaValle, 1935).

Occupational exposures to talc dust in mines and mills in New York State, USA, have been studied extensively (Siegal *et al.*, 1943; Kleinfeld *et al.*, 1955; Messite *et al.*, 1959; Kleinfeld *et al.*, 1967, 1974; Dement & Zumwalde, 1979; Dement *et al.*, 1980). Talc deposits in the state have been found to differ significantly in mineral composition, depending on location. Siegal *et al.* (1943) reported that talc produced in St Lawrence County contained tremolite, anthophyllite and only traces of quartz, and described the particle morphology as straight, needle-like fibres with a maximum length of 15 μm . Kleinfeld *et al.* (1973) also reported the major fibrous components of these talcs to be tremolite and anthophyllite, based on detailed electron microscopic observations. Bulk talc samples from another mine and mill in upper New York State were analysed for mineral content by optical petrographic microscopy, electron microscopy and X-ray diffraction. The mineral composition (by weight) of the talc bulk samples was 14-48% talc, 37-59% tremolite (including both fibrous and nonfibrous habits), 4.5-15% anthophyllite (including both fibrous and nonfibrous habits), 0.25-2.6% free silica, 0.0-1% calcite, 0.5-1% dolomite and 10-15% serpentines (largely lizardite and antigorite) (Dement & Zumwalde, 1979; Dement *et al.*, 1980).

Talc dust and fibre exposures in mining and milling operations in St Lawrence County, NY, for the period 1945-1972 are summarized in Table 8. Prior to dust control measures, such as wet drilling, average exposures to mine dust ranged from 120-818 mppcf; after 1945, these were reduced to 5-19 mppcf. Exposures in mills prior to 1945 ranged from 69-278 mppcf; average exposures in 1972 ranged from 7-36 mppcf. In 1972, optical fibre counts, using membrane-filter sampling and analyses, revealed that exposures in mines were low

Table 7. Studies of occupational exposures to talc

Reference	Industry studied	Location of talc deposit	Date of exposure measurements	Measurement method employed	Other minerals present in talc studied
Dreessen (1933)	Mining/Milling	Georgia, USA	Pre 1933	Impinger	Tremolite
Dreessen & DallaValle (1935)	Mining/Milling	Georgia, USA	Pre 1935	Impinger	Tremolite, dolomite
Siegal <i>et al.</i> (1943)	Mining	New York, USA	1940-1941	Impinger	Tremolite, anthophyllite, traces of free silica
Kleinfield <i>et al.</i> (1955); Messite <i>et al.</i> (1959); Kleinfield <i>et al.</i> (1967, 1974)	Mining/Milling	New York, USA	Pre 1945-1972	Impinger	Tremolite, anthophyllite, carbonates, traces of free silica
Kleinfield <i>et al.</i> (1973)	Mining/Milling	New York, USA	1954-1970	Impinger, optical fibre counts	Tremolite, anthophyllite
Dement & Zumwalde (1979); Dement <i>et al.</i> (1980)	Mining/Milling	New York, USA	1975	Gravimetric, optical and electron microscopy fibre counts	Tremolite, calcite, anthophyllite, dolomite, serpentines, silica
Rubino <i>et al.</i> (1976)	Mining/Milling	Piedmont, Italy	1920-1975	Impinger	Small amounts of tremolite
Boundy <i>et al.</i> (1979)	Mining/Milling	Vermont, USA	1975-1976	Optical and electron microscopy fibre counts	Dolomite, calcite, magnesite, chlorite, traces of other minerals
Greife (1980); Gamble <i>et al.</i> (1982)	Mining/Milling	Montana, Texas and North Carolina, USA	1977-1980	Gravimetric	Varied by location studied
Hogue & Mallette (1949)	Rubber dusting	Vermont, USA	1943-1948	Impinger	Stated to be 'pure talc'
Dement & Shuler (1972)	Rubber dusting	Not stated (USA)	1972	Gravimetric, optical fibre counts	2-3% free silica
Fine <i>et al.</i> (1976)	Rubber dusting	Vermont, USA	1972-1974	Gravimetric	Trace of silica (<1%), <2 fibres/cm ³

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Table 8. Average dust and fibre concentrations in St Lawrence County, NY, talc mining and milling operations, pre-1945-1972^a

Exposure	Dust exposure (mppcf)				Fibres ^b
	Before 1945	1946-1965	1966-1969	1972	1972
<i>Mining</i>					
Drilling	818	5	19	7	3
Mucking	120	5	9	3	2
<i>Milling</i>					
Crushing	180	42	28	35	62
Screening	69	37	—	—	—
Milling	92	25	40	7	25
Garnering and separating	278	27	—	13	27
Pulverizing	—	28	—	—	—
Bagging	151	27	29	27	47
Box car and lorry loading	—	73	43	36	24

^aFrom Kleinfeld *et al.* (1974)^bNumber of fibres/cm³ >5 μ m in length (by phase-contrast microscopy)

(2-3 fibres >5 μ m/cm³), whereas exposures in mills ranged from 25-62 fibres/cm³ (Kleinfeld *et al.*, 1974). [The Working Group noted that the fibre counts represent optical counts of all fibres with a 3:1 aspect ratio and longer than 5 μ m, with no further mineral identification.]

Data on time-weighted-average exposures to respirable dust and airborne fibres in the mine and mill studied by Dement *et al.* are shown in Table 9. Time-weighted average exposures to respirable dust ranged from 0.23-1.29 mg/m³ in the mine and 0.25-2.95 mg/m³ in the mill. Due to the low free silica content of this talc, exposure to respirable free silica did not exceed 0.025 mg/m³ in the mine and 0.028 mg/m³ in the mill. Airborne fibre levels measured by optical microscopy gave mean exposures in the mine and mill of 4.5 and 5.0 fibres >5 μ m/cm³, respectively, with peak values as high as 29.1 fibres/cm³ in the mill. Further analyses of the airborne fibre samples by electron microscopy showed that 65% of the fibres greater than 5 μ m in length were anthophyllite and 7% were tremolite. The authors concluded that the most important fibrous component of this talc deposit was anthophyllite (Dement & Zumwalde, 1979; Dement *et al.*, 1980).

Concentrations of respirable dust in mass samples from three Vermont talc mines and mills surveyed in 1975-1976 are given in Table 10. Geometric mean exposures to respirable dust ranged from 0.5 to 5.1 mg/m³ in the mines and from 0.5 to 2.9 mg/m³ in the mills; however, exposures in the mills were generally higher than those in the mines. Optical fibre counts of as much as 60 fibres/cm³ were reported. Subsequent analyses of these samples by scanning electron microscopy demonstrated rolled talc and elongated talc particles. X-ray diffraction analyses of bulk samples from these mines and mills showed that talc and magnesite were the major (20-100%) mineral components, chlorite and dolomite minor (5-20%) components, and that dolomite, calcite, quartz, biotite, ankerite, chromite,

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Table 9. Respirable dust exposures and airborne fibre (longer than 5 μm) concentrations^a in a New York state talc mine and mill^b

Operation	Respirable dust				Airborne fibres				
	No. of samples	Time-weighted average ^c		Highest peak ^d (mg/m ³)	No. of samples	Time-weighted average ^c			Highest peak ^d (fibres >5 $\mu\text{m}/\text{cm}^3$)
		Mean	Range			Mean	Median	Range	
Mine	14	0.86	0.23-1.29	1.72	54	4.5	4.4	0.8-9.8	18.2
Mill	29	0.86	0.25-2.95	4.64	168	5.0	4.3	0.2-16.0	29.1

^aBy optical microscopy^bFrom Dement and Zumwalde (1979)^cFull shift determinations^dBased on highest concentration observed in a single sample**Table 10. Respirable dust concentrations (mg/m³) in Vermont talc mines and mills^a**

Company	Area	Summer 1975		Winter 1976	
		No. of samples	Geometric mean (mg/m ³)	No. of samples	Geometric mean (mg/m ³)
A	Underground mine	18	0.6	16	0.5
	Mill (1st shift)	4	1.7	13	1.7
	Mill (2nd shift)	6	0.5	3	1.5
B	Underground mine	15	1.5	23	0.9
	Mill (1st shift)	22	1.8	42	1.8
	Mill (2nd shift)	12	2.9	16	1.9
C	Underground mine	12	0.5	19	0.7
	Walk-in mine	7	1.2		
	Walk-in mine			6	1.7
	Open-pit mine	2	5.1	—	—
	Mill # 1 (1st shift)	12	0.9	20	1.1
	Mill # 1 (3rd shift)	3	0.8	4	1.4
	Mill # 2 (1st shift)	11	1.0	8	0.5
	Mill # 2 (2nd shift)	13	0.8	3	1.1

^aFrom Boundy *et al.* (1979)

phlogopite and oligoclase were present in smaller amounts (<5%). Trace amounts of free silica were found in 15% of the samples (Boundy *et al.*, 1979). One closed mine was reported to contain tremolite microinclusions, but its fibrosity was not documented (Selevan *et al.*, 1979).

A cross-sectional study of occupational exposures in US talc mines and mills was conducted by the National Institute for Occupational Safety and Health; the results are summarized in Table 11. Bulk samples from each region were analysed by transmission electron microscopy: no fibre was found in any sample of Montana talc; fibrous tremolite and antigorite were reported in Texan talcs (0.5-3.0 μm in diameter, 4-30 μm in length); and talcs from North Carolina contained acicular cleavage fragments with particle length: diameter ratios as high as 100:1, with some <0.1 μm in diameter (Greife, 1980; Gamble *et al.*, 1982).

Table 11. Respirable dust concentrations in 275 samples from talc mines and mills located in Montana, Texas and North Carolina, USA^a

Samples	Geometric mean (mg/m ³)		
	Montana	Texas	North Carolina
From mines	0.66 (0.47-0.92) ^b	0.45 (0.18-0.71)	0.14 (0.07-0.31)
From mills	1.1 (0.85-1.41)	1.56 (0.96-2.54)	0.26 (0.13-0.51)
Bulk talc samples (% free silica)	<0.8	2.23	1.45

^aAdapted from Greife (1980) and Gamble *et al.* (1982)

^bIn parentheses, 95% frequency interval

Analysis of 362 personal samples of respirable dust collected over a full shift by the Mine Safety and Health Administration from talc mines and mills in the USA showed the median dust exposure to be 1.20 mg/m³; 90% of all exposures were to less than 2.78 mg/m³ (National Institute for Occupational Safety and Health, 1979).

Prior to adoption of technical preventive means in 1950, exposures in the talc operation in the Germanasca and Chisone Valley (Piedmont), Italy, were reported to be to approximately 800 mppcf in the mines and to 25 mppcf in the mills. Exposures in both areas were reduced to less than 10 mppcf after 1965. Mineralogical analyses of these talcs demonstrated that they contained quartz, muscovite, chlorite, garnet, calcite, magnesite and small quantities of other minerals. In a few specimens, a small amount of tremolite was detected, but no other type of amphibolic asbestos or chrysotile was reported. The free silica content of powdered talc specimens was generally below the detection limits of X-ray diffraction (Rubino *et al.*, 1976). [The Working Group noted that the analytical methods were not described in detail, and the relative fibrosity of the tremolite was not documented.]

Only limited information is available about exposures in secondary industries in which talc is used or processed further. Personal air samples collected in a rubber band production plant, where housekeeping, ventilation and work practices were poor and in which talc was used as an antistick agent, had time-weighted average respirable dust concentrations of 2.5-7.8 mg/m³ (average, 4.8 mg/m³) for extruders, 5.3 and 6.1 mg/m³ for vulcanizers and 0.9 and 1.3 mg/m³ for cutters. Total dust exposures were found to range from 5.4-199 mg/m³. The talc was reported to contain 2-3% free silica. Fibre exposures, as measured by phase-contrast optical microscopy, ranged from 4.7-19.2 fibres >5 µm/cm³ (Dement & Shuler, 1972). [The Working Group noted that no electron microscopic analysis was conducted to confirm the identity of the fibres; however, most of the fibres were probably not asbestos.]

Respirable dust concentrations in two rubber manufacturing plants where Vermont talc was used as an antistick agent are shown in Table 12. Eighteen of 21 samples analysed for free silica contained less than 1% by weight. In 12 samples analysed for fibres, using optical microscopic techniques for asbestos, all concentrations were less than 2 fibres >5 µm/cm³. No electron microscopic fibre analysis was reported (Fine *et al.*, 1976). Hogue and Mallette (1949) found an average dust concentration of 15-50 mppcf talc in two rubber plants using Vermont talc. Tube machine operators had an average exposure of 20 mppcf; tube 'bookers', 35 mppcf; tube cure men, 15 mppcf; and 'line rerollers', 50 mppcf.

Table 12. Respirable dust concentrations in rubber processing plants using talc^a

Location	No. of samples	Average dust concentration (mg/m ³)
<i>Plant A</i>		
Lorry and bus inner tubes (splicer)	7	0.60
Lorry and bus inner tubes (cureman)	6	1.41
'Tuber operator'	3	0.47
'Booker'	3	0.74
Farm service inner tubes (splicer)	6	0.82
Farm service inner tubes (cureman)	2	0.91
<i>Plant B</i>		
Rubber band area	6	3.55
Gum engraving room	6	0.64
Hose extruding	4	0.51
Curing heavy duty flaps	3	1.29
'Dust room'	2	0.59

^aFrom Fine *et al.* (1976)

2.3 Analysis

Because talc is frequently contaminated with a number of other mineral phases, some known to be biologically active, an analytical protocol is often required that can distinguish among these phases.

Phase-contrast optical microscopy is a conventional technique for the identification of minerals. A microscope equipped with bright-field illumination and polarized light optics may be used to analyse talc powders (Hamer *et al.*, 1976; Boundy *et al.*, 1979; Rohl & Langer, 1979). The limitations of the technique for this purpose are discussed by Rohl *et al.* (1976).

The characteristic lines of X-ray powder diffraction pattern are 0.934, 0.468, 0.456, 0.343, 0.3115, 0.2632 and 0.2598 nm (Ross, 1984). Quantitative mineralogical analyses of bulk samples are sensitive to about 1-2% of talc (Pooley & Rowlands, 1977). The application of X-ray diffraction analysis, both continuous and step-scan modes, for quantitative determination of contaminating minerals in talc has been described, including the selection of talc and reference materials, the preparation of standard dilutions of fibres in talc to ensure sensitivity and reproducibility, the selection of characteristic X-ray reflections to be scanned, and instrumental technique. Tremolite, chrysotile and anthophyllite impurities in talc can be determined at levels as low as 0.1-2% (Rohl & Langer, 1974; Rohl *et al.*, 1976).

Morphological, structural and chemical information on single particles of talc and associated minerals can be obtained by analytical electron microscopy and selected-area electron diffraction (Rohl *et al.*, 1976).

3. Biological Data Relevant to the Evaluation of Carcinogenic Risk to Humans

3.1 Carcinogenicity studies in animals¹

The Working Group noted that in most of the studies of 'talc' described below, no or limited characterization of the mineralogy of the sample employed was given, and, in particular, there was a lack of information on fibre content or particle size.

(a) Oral administration

Rat: Groups of 25 male and 25 female Wistar rats, ten weeks of age, received about 50 mg/kg bw per day commercial talc [characteristics unspecified] in the diet or standard diet for life (average survival, 649 days). No significant difference in tumour incidence was found in comparison with controls (Gibel *et al.*, 1976).

A group of 16 male and 16 female Wistar-derived rats, 21-26 weeks of age, were exposed to 100 mg Italian talc (grade 00000; ready milled; mean particle size, 25 μ m; containing

¹The Working Group was aware of studies in progress in mice and rats by inhalation (IARC, 1986) and in rats by subcutaneous and intraperitoneal injection (Maltoni *et al.*, 1982).

92% talc, 3% chlorite, 1% carbonate minerals and 0.5-1% quartz) per day per rat in the diet for five months and then maintained on basal diet for life (average survival, 614 days). A control group of 16 rats was fed basal diet. No difference in tumour incidence was found between the two groups (Wagner *et al.*, 1977). [The Working Group noted the limited exposure period and the advanced age of the animals at the start of exposure.]

(b) *Inhalation exposure*

Rat: A group of 24 male and 24 female Wistar-derived rats, six to eight weeks of age, was exposed by inhalation to a mean respirable dust concentration of 10.8 mg/m³ Italian talc (grade 00000; ready milled; mean particle size, 25 µm; containing 92% talc, 3% chlorite, 1% carbonate minerals and 0.5-1% quartz) for 7.5 h per day on five days a week for six (24 rats) or 12 (24 rats) months (cumulative exposures, 8200 and 16 400 mg/m³ × h, respectively). Ten days after the end of each exposure period, six rats in each group were killed; a further four rats were killed in each group one year later. Within 28 months of the start of the study, a further 12 animals in each group had died. No lung tumour was observed in rats exposed to talc for six months, while one lung adenoma occurred among those exposed for 12 months. No lung tumour was found in 24 male or 24 female controls (Wagner *et al.*, 1977). [The Working Group noted the limited number of animals allowed to survive longer than 12 months after the end of each exposure period.]

Hamster: Three groups of 50 male and 50 female Syrian golden hamsters, four weeks old, were exposed to an aerosol of talc baby powder, prepared from Vermont talc by flotation (95% w/w platy talc with trace quantities of magnesite, dolomite, chlorite and rutile), for 3, 30 or 150 min per day on five days a week for 30 days. The mean total aerosol concentration was 37.1 mg/m³, with a mean respirable fraction of 9.8 mg/m³ and a mass median aerodynamic diameter of 4.9 µm. Two further groups of hamsters, seven weeks old, were exposed to talc aerosol for 30 or 150 min per day for 300 days or until death. The mean total aerosol concentration was 27.4 mg/m³, with a mean respirable fraction of 8.1 mg/m³ and a mass median aerodynamic diameter of 6 µm. Two control groups of 25 males and 25 females were sham exposed. No primary neoplasm was found in the respiratory system of any hamster. The incidence of alveolar-cell hyperplasia was 25% in the groups exposed to aerosol for 30 or 150 min per day for 300 days, compared with 10% in the control group (Wehner *et al.*, 1977a, 1979). [The Working Group noted the inadequate duration of the study.]

(c) *Intratracheal administration*

Hamster: Groups of 24 male and 24 female Syrian golden hamsters, nine weeks old, received 18 weekly intratracheal injections of 3 mg talc (United States Pharmacopeia grade; 93.3% below 25 µm) in 0.2 ml saline, with or without 3 mg benzo[*a*]pyrene, or 0.2 ml saline only, or were untreated. The animals were allowed to live out their lifespan (average 50% survival, 46-55 weeks). No respiratory-tract tumour was observed in animals exposed to talc alone or in saline-treated or untreated controls. In hamsters exposed to talc with benzo[*a*]pyrene, 33/45 animals had benign and malignant tumours of the respiratory tract

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(larynx to lung) (Stenbäck & Rowland, 1978). [The Working Group noted that no group received benzo[a]pyrene alone and that the survival in all groups was relatively short.]

(d) *Subcutaneous administration*

Mouse: Fifty female R3 mice, three to six months of age, were given single subcutaneous injections of 0.2 ml of a mixture of 8 g talc [unspecified] and 20 g peanut oil [dose, about 80 mg] and observed for life (average 50% survival, 596 days). No local tumour was observed (Neukomm & de Trey, 1961).

In a study reported in an abstract, female Marsh mice, three months old, received single subcutaneous injections of 20 mg USP talc and were observed for 18-21 months. No tumour developed at the injection site in 26 treated animals or in 24 saline-injected controls (Bischoff & Bryson, 1976).

(e) *Intraperitoneal administration*

Mouse: In a study reported in an abstract, female Marsh mice, three months old, received single intraperitoneal injections of 20 mg USP talc and were observed for 18-21 months. Intraperitoneal lymphoid tumours occurred in 5/22 treated animals and in 6/28 saline-treated controls (Bischoff & Bryson, 1976).

Forty Swiss albino mice [sex unspecified], six weeks of age, received single intraperitoneal injections of 20 mg ground commercial talc [unspecified] in saline. Before six months, 16 animals had died. In the 24 survivors allowed to live out their normal lifespan [unspecified], three peritoneal mesotheliomas were observed, compared with 3/46 in saline-treated controls (Özesmi *et al.*, 1985). [The Working Group noted the inadequate reporting of the study.]

Rat: A group of 40 female Wistar rats, eight to 12 weeks of age, received four intraperitoneal injections of 25 mg granular talc in 2 ml saline at weekly intervals. A group of 80 female rats injected with saline served as controls. The rats were observed until spontaneous death or sacrifice (average survival time after injection, 602 days). A mesothelioma was observed in 1/36 talc-exposed rats after 587 days compared with none in 72 controls (Pott *et al.*, 1974, 1976a,b).

In a study reported in an abstract, three-month-old female Evans rats received single intraperitoneal injections of 100 mg USP talc and were observed for 18-21 months. Of the treated rats, 3/27 developed tumours (one lymphosarcoma, one reticulum-cell sarcoma in the peritoneal cavity, one cystadenoma of the liver), compared with none in 26 saline-treated controls (Bischoff & Bryson, 1976).

(f) *Intrapleural and intrathoracic administration*

Mouse: In a study reported in an abstract, male Marsh mice, three months old, received single intrathoracic injections of 10 mg USP talc. After 18-21 months, 5/47 treated mice had tumours (two adenocarcinomas and three lymphoid tumours of the lung), compared with none of 48 saline-injected controls (Bischoff & Bryson, 1976).

Rat: In a study reported in an abstract, female Evans rats, three months old, received single intrathoracic injections of 50 mg USP talc. After 18-21 months, intrathoracic reticulum-cell sarcomas or lymphomas were observed in 7/30 talc-treated rats, in 8/32 saline-treated animals and in 7/28 untreated controls (Bischoff & Bryson, 1976).

A group of 24 male and 24 female Wistar-derived rats, eight to 14 weeks old, received single intrapleural injections of 20 mg Italian talc (grade 00000; ready milled; mean particle size, 25 μ m; containing 92% talc, 3% chlorite, 1% carbonate minerals and 0.5-1% quartz). The mean survival time of the treated rats (655 days) was similar to that of 24 male and 24 female controls (691 days) injected with saline. No mesothelioma was detected in either group; one small pulmonary adenoma was found in one rat that died 25 months after injection (Wagner *et al.*, 1977).

Groups of 30-50 female Osborne-Mendel rats, 12-20 weeks old, received single intrapleural implantations of 40 mg of one of seven grades of refined commercial talc from separate sources in hardened gelatin. The rats were followed for two years, at which time survivors were killed. The incidences of pleural sarcomas were: talc 1, 1/26; talc 2, 1/30; talc 3, 1/29; talc 4, 1/29; talc 5, 0/30; talc 6, 0/30; talc 7, 0/29; compared with 3/491 in untreated controls, 17/615 in controls receiving implants of 'nonfibrous' materials described by the authors as 'noncarcinogenic' and 14/29 in rats receiving UICC crocidolite asbestos (Stanton *et al.*, 1981).

3.2 Other relevant biological data

(a) *Experimental systems*

Toxic effects

A review of the literature prior to 1978 on the biological effects of talc is available (Lord, 1978).

The Working Group noted that in most of the studies of 'talc' described below, no or limited characterization of the mineralogy of the sample employed was given, and, in particular, there was a lack of information on fibre content or particle size.

(i) *Lethality*

The LD₅₀ of talc has not been established unequivocally.

Significant mortality was observed in guinea-pigs after two or three intravenous injections of 25 mg talc in saline (Dogra *et al.*, 1977). In contrast, there was no treatment-related death in rabbits injected intravenously daily for two weeks with 100 mg talc in saline (Puro *et al.*, 1966), in rabbits receiving twice-weekly intravenous injections of 50 mg talc for ten weeks or in rats receiving twice-weekly intravenous injections of talc over a nine-week period (total dose, 100 mg) (Schepers & Durkan, 1955b). Three of 11 rats died within one day following injection of 1400 mg/kg bw talc into the lower pole of the spleen (Eger & Da Canal, 1964).

In most of the studies described below, no acute mortality was observed in several species of animals following administration of high doses of talc by ingestion, inhalation or intratracheal, intrapleural, intraperitoneal or subcutaneous injection.

In rats fed 100 mg talc per day for 101 days, no significant depression of mean lifespan was observed (Wagner *et al.*, 1977).

Several studies of exposure to talc *via* inhalation have been reported; but, until recently (see Hanson *et al.*, 1985), the primary technical problem associated with inhalation experiments has been a lack of methods to determine accurately the amount of talc inhaled by exposed animals. The acute mortality observed in rats exposed to a 'very dense' cloud of talc (particle size, $<5 \mu\text{m}$) for 3 h per day for up to 12 days may have been due to suffocation (Policard, 1940). None of a group of rats exposed to 30-383 mg/m³ 'technical'- or 'pharmaceutical'-grade talc for 6 h per day on six days per week for up to nine months died as a specific consequence of exposure (Bethge-Iwańska, 1971). No effect was observed on the survival of hamsters exposed by inhalation to 8 mg/m³ respirable 'baby talc' for up to 150 min per day on five days per week for 300 days (Wehner *et al.*, 1977a, 1979).

A 79% mortality rate was reported in rats receiving a single intratracheal injection of 50 mg/ml talc in water. Subsequently, it was found that rats could tolerate the dose if they were given two injections of 25 mg/0.5 ml at weekly intervals (Lüchtrath & Schmidt, 1959). A 40% mortality was observed in rats injected intratracheally with 25 mg tremolitic talc/ml water (Gross *et al.*, 1970). Low mortality (2/14) was reported in chinchillas given five intratracheal injections of 40 mg talc in saline (both deaths occurred after the first injection) (Trautwein & Helmboldt, 1967).

No significant mortality was observed following intrapleural injection of 20 mg talc in saline into rats (Wagner *et al.*, 1977). Increased mortality was reported in mice six months after intraperitoneal injection of 20 mg 'commercial' talc in saline (Özesmi *et al.*, 1985), but no increased mortality was observed in rats injected intraperitoneally with 100 mg talc in saline (Pott *et al.*, 1976a). No acute toxicity was observed after a single injection of 10 mg into the bursa of rats (Hamilton *et al.*, 1984) or after suprascapular subcutaneous injection of 600 mg into mice (Carson & Kaltenbach, 1973). Transient convulsions were observed in rabbits following cisternal injection of 1 ml of a 1:9 or 1:4 suspension of talc in saline (Oppenheimer & Riester, 1953).

(ii) *Chronic toxicity*

Mild to marked arterial endothelial cell proliferation with cellular encroachment into the lumen and the occurrence of occasional foreign-body giant cells within the endothelial masses were observed after daily intravenous injections of 100 mg talc for two weeks to rabbits (Puro *et al.*, 1966). After three intravenous doses of 25 mg talc in saline to guinea-pigs, mild proliferation of the endothelial cells and moderate thickening of the intra-alveolar septa of the lungs were observed 150 days after injection (Dogra *et al.*, 1977). In contrast, no effect on the rat lung was observed after intravenous injection of talc (Schepers & Durkan, 1955b). Talc granulomas were observed in the region of Glisson's capsule following intrasplenic injection of 1400 mg/kg talc to rats (Eger & Da Canalis, 1964). After cisternal injection of talc to rabbits, no permanent neurological disorder was

seen. Microscopic examination revealed a phagocytic, histiocytic response, with some fibroblastic proliferation and dense adhesions between the membranes (Oppenheimer & Riester, 1953).

No chronic pathological effect was associated with oral administration of talc to rats (Wagner *et al.*, 1977). Intratracheal injections of talc (total dose, 150 mg) to guinea-pigs induced perivascular and peribronchiolar focal accumulations of histiocytes, fibrocytes, plasma cells and eosinophils within one month; by eight months, some fibrosis, with fibrocellular sclerosis of the pleural surface, was observed. After two years, the dominant effects were bronchiolectasia, bronchiolitis and marked fibrosis (Schepers & Durkan, 1955b).

No evidence of lung fibrosis or lymph node abnormality was observed in rats given a single intratracheal injection of 50 mg 'pure' talc in water; however, rats that received the same dose of 'calcined' (1000-1100°C) talc developed lung and lymph node fibrosis after 13 months (Lüchtrath & Schmidt, 1959). Proliferative inflammation of the smaller bronchi and bronchioles was observed in rats four days after intratracheal injection of 25 mg talc (containing tremolite; fibres, 0.1-0.2 μm in diameter) in water; within a few months, collagenous tissue had been formed (Gross *et al.*, 1970).

Chinchillas receiving a single or several intratracheal injections of 40 mg 'purified' talc in saline exhibited chronic pulmonary irritation and proliferative pneumonia, with giant-cell granulomas and adjacent metaplasia of the alveolar epithelium. The hyperplastic cells subsequently transformed into cuboid cells that formed a continuous lining of the affected alveoli and finally acquired an adenomatous appearance (Trautwein & Helmboldt, 1967).

Exposure by inhalation to a 'heavy dosing' of talc was badly tolerated by rats, causing severe dyspnoea. However, no histological change was observed within 20 days, and talc particles were trapped by alveolar macrophages (Policard, 1940). Rats exposed to dust clouds of 30-383 mg/m^3 'industrial'- or 'pharmaceutical'-grade talc for nine months developed chronic inflammatory changes, including thickening of the pulmonary arteries walls and, eventually, emphysema (Bethge-Iwańska, 1971).

In rats exposed by inhalation to 10.8 mg/m^3 Italian talc (grade 00000; ready milled; mean particle size, 25 μm) for three months, minimal fibrosis was observed, the degree of which did not change during the post-exposure period. Animals exposed for one year had minimal to slight fibrosis, the degree of which had increased to moderate within one year after cessation of exposure (Wagner *et al.*, 1977). In contrast, Syrian golden hamsters exposed to 8 mg/m^3 talc aerosols for up to 150 min per day on five days per week for 30 days showed no histopathological change in the lungs, heart, liver, renal tissues, stomach or uterus (Wehner *et al.*, 1977a, 1979; Wehner, 1980).

Injection of 10 mg talc (containing some asbestos fibres) into the pleural cavity of mice has been reported to produce granulomas, some of which were firmly attached to the surface of the lungs or other chest contents and, occasionally, to the lung lobes (Davis, 1972). Two years after injection of 20 mg Italian talc (see above) into the right pleural cavity of rats, granulomas at the injection site were common, and one small pulmonary adenoma was observed, but no other relevant pathology was observed in the lungs (Wagner *et al.*, 1977).

Guinea-pigs received single intraperitoneal injections of 200 mg of one of seven 'industrial'-grade talcs (up to 52% talc, up to 82% tremolite, traces of quartz). Nodules consisting of macrophages and giant cells were first observed at ten days on the ventral parietal surface and over a 15-month period became smaller. Fibroblastic proliferation was pronounced in the early phases (Schulz & Williams, 1942).

Six months after intraperitoneal injection of approximately 400 mg of a talcum powder used on surgical gloves, laparotomized albino rats exhibited typical granulomas with numerous foreign-body giant cells (Blümel *et al.*, 1962). These findings were confirmed in rats implanted with suture material dusted with talc or talc pellets, which resulted in a chronic inflammatory process with persistent granuloma formation (Sheikh *et al.*, 1984).

(iii) *Toxicity in vitro*

The concentration of talc (99% pure) required to cause 50% haemolysis of red-blood cells was 65 mg/ml, which is more than 50 fold that of chrysotile (Woodworth *et al.*, 1982).

Mouse peritoneal macrophages were exposed to seven different specimens of talc (only one of which contained amphibole fibres); all seven were found to be 'modestly' cytotoxic, as determined by the release of lactate dehydrogenase and β -glucuronidase, to a degree ten-fold less than quartz. No statistical difference was reported for the effects of the different talc samples (Davies *et al.*, 1983). The phagocytosis of talc by rabbit lung fibroblasts has been reported (Henderson *et al.*, 1975a).

A concentration of 0.1 mg/ml talc (99% pure) caused 35% release of ^{51}Cr from Syrian hamster tracheal epithelial cells labelled with sodium chromate; the concentration is two-fold that required for chrysotile (Woodworth *et al.*, 1982).

A concentration of $>50 \mu\text{g/ml}$ Italian talc caused a 50% reduction in the colony-forming efficiency of Chinese hamster V79-4 lung cells (Chamberlain & Brown, 1978).

Effects on reproduction and prenatal toxicity

Talc was found to produce nonspecific abnormalities in chicken eggs, at an incidence similar to that induced by thalidomide and sulphadimethoxine (Carter, 1965; Yang, 1977).

No teratological effect was observed in hamsters, rats, mice or rabbits following oral administration of talc. The doses used were 1600 mg/kg bw to rats and mice on days 6-15 of gestation; 1200 mg/kg bw per day to hamsters on days 6-10 of gestation; and 900 mg/kg bw to rabbits on days 6-18 of gestation (Food and Drug Research Laboratories, 1973).

Deposition, retention and clearance

The deposition, translocation and clearance of talc in hamsters was followed by giving them a single nose-only inhalation exposure for 2 h to 40-75 mg/m³ neutron-activated talc (median diameter based on radioactivity measurements, 6.4-6.9 μm). High-grade cosmetic talc was used, consisting of 95% (w/w) platy talc mineral. Alveolar deposition was approximately 20-80 μg , representing 6-8% of the inhaled amount. The biological half-life of the talc deposited in the alveoli was seven to ten days, and alveolar clearance was reported to be essentially complete four months after exposure. [The Working Group noted that the unusually short clearance time may relate to limitations in the sensitivity of the detection

methods and the large size of the particles used.] No translocation of talc to liver, kidneys, ovaries or other parts of the body was found (Wehner *et al.*, 1977a,b).

In rats exposed to aerosols (mean respirable dust, 10.8 mg/m³) of Italian talc (see above), the mean amounts of talc retained in the lung were 2.5, 4.7 and 12.2 mg per rat following exposures for three, six and 12 months, respectively. These levels were roughly proportional to the cumulative exposures (Wagner *et al.*, 1977). In rats exposed for 6 h per day on five days per week for four weeks to 2.3, 4.3 and 17 mg/m³ respirable talc, the amounts retained in the lung at the end of exposure were 77, 187 and 806 µg talc per g lung, respectively (Hanson *et al.*, 1985).

Talc, like other foreign particles, has been found to depress the clearance of 3,4-benzo[*a*]pyrene from the lungs of hamsters (Pelfrene, 1976).

Guinea-pigs were given a single intraperitoneal injection of 200 mg of one of seven commercial talc samples (containing 3-52% talc, the rest being serpentines, carbonate, quartz and tremolite; 82% tremolite in one sample) and were examined at intervals up to 15 months. Because of differences in solubility, there was relative enrichment of the sample with talc. Talc particles were found mainly on the ventral parietal surface of the peritoneum within macrophages and giant cells (Schulz & Williams, 1942).

In studies in rats, mice, guinea-pigs and hamsters using radioactive tracer techniques, no intestinal absorption or translocation of ingested talc to the liver and kidneys was detected (Wehner *et al.*, 1977c; Phillips *et al.*, 1978). No translocation of talc into the ovaries was detected after single or multiple intravaginal applications to rabbits (Phillips *et al.*, 1978).

Mutagenicity and other short-term tests

Talc was not mutagenic to *Salmonella typhimurium* TA1530 or *his* G46 or to *Saccharomyces cerevisiae* D3 *in vitro* [full details not given] or in host-mediated assays in mice (30-5000 mg/kg bw) (Litton Bionetics, 1974).

Chromosomal aberrations were not induced in human WI38 cells treated with talc at 2-200 µg/ml, and neither chromosomal aberrations nor dominant lethal mutations were induced in rats following oral administration of 30-5000 mg/kg bw talc (Litton Bionetics, 1974).

Single intraperitoneal injections of 20 mg talc plus 2 mg particulate prednisolone acetate in saline into mice induced significant numbers of multinucleated giant cells within 48 h. Neither compound alone induced this response. The multinucleate cells arose by cell fusion, and the resultant polykarions exhibited severe structural chromosomal abnormalities (bridges, acentrics and dispersed chromosomes). Prednisone in combination with talc also elicited the formation of multinucleated giant cells. Polykarions were not observed when talc was injected in combination with cortexone acetate, cortisone or testosterone isobutyrate (Dreher *et al.*, 1978).

(b) Humans

Toxic effects

The toxic effects of talc are dependent on the route, dose and properties of the talc

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involved. In addition, talc commonly contains other minerals (see section 1.3), including in some instances several forms of asbestos and silica.

Talc pneumoconiosis is somewhat more prevalent and severe among people exposed to talc containing asbestiform minerals than among those exposed to talc without such impurities (Schepers & Durkan, 1955a; Kleinfeld *et al.*, 1963). The form of the pneumoconiosis varies widely, from an asymptomatic simple type (Buus-Hansen *et al.*, 1950; Vallyathan & Craighead, 1981) to disabling conglomerate pneumoconiosis (Jaques & Benirschke, 1952; Hunt, 1956; Graham & Gaensler, 1965; Fristedt *et al.*, 1968; Miller *et al.*, 1971). Mixed-dust pneumoconiosis is frequently seen, including silicosis, asbestosis and occasionally other forms (Porro *et al.*, 1942; Schepers & Durkan, 1955a; Kleinfeld *et al.*, 1963; Mark *et al.*, 1979).

Several early reports describe 'talcum powder granuloma' arising from the use of talc on surgical gloves (Antopol, 1933; Fienberg, 1937; German, 1943; Eiseman *et al.*, 1947; Diffenbaugh, 1953; Henderson *et al.*, 1975b). Subsequent cases have been reported which document a variety of surgical complications, including adhesions, pseudotumours and sinus tracts attributable to talc exposure (Lichtman *et al.*, 1946; Pruvost, 1946; Eiseman *et al.*, 1947; Saxén & Tuovinen, 1947; Enderlin *et al.*, 1959). Both skin granulomas and talc pneumoconiosis have been reported after liberal use of talc on the body (Tye *et al.*, 1966; Nam & Gracey, 1972; Wells *et al.*, 1979; Tukiainen *et al.*, 1984).

Respiratory distress syndrome, which can be fatal, has been described in children following massive accidental inhalation of talcum powder (Cless & Anger, 1954; Molnar *et al.*, 1962; Gouvêa *et al.*, 1966; Hughes & Kalmer, 1966; Lund & Feldt-Rasmussen, 1969; Niemann *et al.*, 1971; Gould & Barnardo, 1972). Acute bronchitis and bronchiolitis were found in a 22-month-old boy who died following accidental inhalation of talc (Molnar *et al.*, 1962).

A variety of pathological effects arise from intravenous use of talc containing drugs by addicts. These include micronuclear pulmonary opacities (Krainer *et al.*, 1962; Hopkins & Taylor, 1970; Szwed, 1970; Arnett *et al.*, 1976; Smith *et al.*, 1978; Waller *et al.*, 1980; Tao *et al.*, 1984), angiothrombotic pulmonary hypertension (Wendt *et al.*, 1964; Bainborough & Jericho, 1970; Zientara & Moore, 1970; Arnett *et al.*, 1976; Paré *et al.*, 1979; Waller *et al.*, 1980) and conglomerate pulmonary lesions (Sieniewicz & Nidecker, 1980; Crouch & Churg, 1983). Reduced pulmonary function has also been observed (Paré *et al.*, 1979). In addition, retinopathy, cerebral microembolization and granulomas of the liver, lymph nodes and kidneys have been reported (Lee & Sapira, 1973; Min *et al.*, 1974; Paré *et al.*, 1979; Carman, 1985).

Two studies by the US Public Health Service (Dreessen, 1933; Dreessen & DallaValle, 1935) of talc containing tremolite showed a high prevalence of pneumoconiosis in workers in talc mines and mills, which appeared to be related to dust concentration and duration of exposure. A variety of pneumoconiotic effects was seen, which did not appear to be related to differences in tremolite content. A series of cross-sectional studies reported from the New York State Department of Labor (Kleinfeld *et al.*, 1955; Messite *et al.*, 1959; Kleinfeld *et al.*, 1963, 1964a,b, 1973) have documented a high prevalence of talc pneumoconiosis in talc miners and millers, especially among tremolitic talc workers. The cases were associated

with pleural plaques, restrictive or obstructive breathing disorders and decreased vital capacity. The prevalence of disease was lower among those with lower cumulative dust exposure and among those processing granular rather than fibrous talc. A large, well-controlled, industry-wide study of miners and millers in four talc deposits in the USA (Gamble *et al.*, 1979a,b; Dement *et al.*, 1980; Gamble *et al.*, 1982) revealed associations between talc containing tremolite and anthophyllite and increased prevalence of bilateral pleural thickening, which was also associated with significant reductions in lung function.

A series of cross-sectional studies describing talc pneumoconiosis in workers in talc mining, milling and manufacture in Italy (Rubino *et al.*, 1963; Tronzano *et al.*, 1965) found that the prevalence was related to extent and duration of exposure and that talcs contaminated with tremolite, serpentine and quartz were associated with significant pneumoconiosis. Similarly, in studies in Egypt (El Ghawabi *et al.*, 1970; Emara *et al.*, 1984), a high prevalence of pneumoconiosis was associated with heavy exposure to talc during milling and in the cosmetics industry; obstructive and restrictive pulmonary impairment were seen among persons with pneumoconiosis.

One reasonably large, representative, well-controlled study of exposure in the rubber industry to Vermont talc, reported to have a low content of silica and fibres, showed significantly increased respiratory symptoms and impaired ventilatory function but no radiographic abnormality (Fine *et al.*, 1976).

Effects on reproduction and prenatal toxicity

No data were available to the Working Group.

Deposition, retention and clearance

Talc particles have been found at autopsy in the lungs of cases of 'talc pneumoconiosis' (Schepers & Durkan, 1955a; Seeler *et al.*, 1959; Kleinfeld *et al.*, 1963; Berner *et al.*, 1981; Vallyathan & Craighead, 1981). Talc, in the form of platy or elongated particles, has been found at autopsy in the lungs of urban residents, farmers, asbestos miners and drug addicts (Seeler *et al.*, 1959; Langer *et al.*, 1971; Pooley, 1976; Abraham & Brambilla, 1979; Gylseth *et al.*, 1984). It has been reported to be concentrated in lung scar tissue (Yao *et al.*, 1984).

Churg and Wiggs (1985) analysed by transmission electron microscopy and energy dispersive X-ray spectroscopy the total fibrous and nonfibrous mineral content of the lungs of a series of 14 male smokers with lung cancer but with no history of occupational dust exposure, and of a series of 14 control men matched by age, smoking history and general occupational class. The average concentrations of mineral fibres and nonfibrous particles were 3.8 and 2.0 times higher in the group with cancer. Kaolinite, talc, mica, feldspars and crystalline silica comprised the majority of fibrous and nonfibrous particles in both groups.

Talc particles were found in stomach tumours from Japanese men (Henderson *et al.*, 1975c), possibly due to ingestion of talc-treated rice (Merliss, 1971a,b). Talc particles, but apparently no other insoluble particle, were found in the subserosal stroma of hernia sacs, possibly due to ingestion of medications in which talc is present as a filler (Pratt *et al.*, 1985).

Talc is used as a filler in some materials that drug addicts inject, resulting in wide dissemination of talc particles to the lung (Groth *et al.*, 1972; Lamb & Roberts, 1972; Farber *et al.*, 1981; Crouch & Churg, 1983), spleen, kidney, liver, brain, heart, adrenal and thyroid (Groth *et al.*, 1972) and even the retina (AtLee, 1972). In lung, most of the talc particles are seen within the vessels of the alveolar walls, and are almost invariably associated with marked foreign body granulomas (Crouch & Churg, 1983). The talc particles found in the lung are larger after intravenous injection than after inhalation (Abraham & Brambilla, 1979).

Mutagenicity and chromosomal effects

No data were available to the Working Group.

3.3 Case reports and epidemiological studies of carcinogenicity to humans

(a) Case reports and case series

Individual case reports of cancer include a lung adenocarcinoma two years following talc pleurodesis (Jackson & Bennett, 1969) and a pleural mesothelioma following occupational exposure to talc (Chahinian *et al.*, 1982; Barz & Beck, 1983; Barnes & Rogers, 1984). [The Working Group noted that either these cases were associated with evidence of asbestos exposure or insufficient environmental data were available to determine whether asbestos exposure had occurred (Chahinian *et al.*, 1982).]

Four cases of mesothelioma reported to the tumour registry of the Cancer Control Bureau, New York Department of Health, USA, were associated with exposure to talc mining. Talc mines in St Lawrence County, New York, contain high levels of fibrous tremolite, the suggested etiological agent (Vianna *et al.*, 1981).

A survey of the long-term effects of talc and kaolin pleurodesis was reported by the Research Committee of the British Thoracic Association and the Medical Research Council Pneumoconiosis Unit (1979). No increase in the number of lung cancer deaths was observed, and no case of mesothelioma was reported. [The Working Group noted that there are several methodological limitations, including the fact that the duration of follow-up was less than 15 years, no data were available on smoking, and no specific information was given on the type or source of talc used.]

(b) Epidemiological studies

Kleinfeld *et al.* (1967, 1974) reported two studies on New York talc miners and millers, the results of which are substantially the same; the more complete 1974 results are reported here. Men employed in 1940, who had accumulated 15 or more years of exposure to commercial talc dust as well as those who achieved a minimum of 15 years of such exposure between 1940 and 1969, were included in this study. The cohort totalled 260 workers and was believed to represent the total work force meeting the exposure criteria. Proportionate mortality was calculated utilizing US white male mortality for the year 1955, the median year of the 108 deaths observed. Environmental exposure was reported to be predominantly to talc containing tremolite and anthophyllite (asbestiform and nonasbestiform habits),

carbonate dusts and a small amount of free silica. Further dust counts were provided for the years 1966-1969: mines had median counts ranging from 9-19 mppcf, and mills, 20-24 mppcf; dust counts and fibre counts reported for the year 1972 ranged from 3-7 mppcf and 2-3 fibres/cm³ in mines and 7-28 mppcf and 24-62 fibres/cm³ in mills. Mortality from lung and pleural cancer showed a three-fold overall increase: observed, 12%; expected, 3.7%. No significant excess was found for gastrointestinal cancers. One peritoneal mesothelioma was noted. [The Working Group noted that, as for the previously reported proportionate mortality study (Kleinfeld *et al.*, 1967), no data were available on smoking or on cumulative dose in individual workers; nor were further data given about the distribution of workers among the several mines and mills from which these records were extracted.]

A cohort mortality study was conducted of 398 white men initially employed between 1 January 1947 and 31 December 1959 in mining and milling talc in the Gouverneur Talc District of Upper New York State (St Lawrence County) (Brown *et al.*, 1979; Dement *et al.*, 1980). In addition to talc, the product contained tremolite, anthophyllite and serpentine minerals, some of which were asbestiform. [Further details of the exposure are reported in section 2.2(b).] Vital status was ascertained as of 1975. Fifty percent of the workers had been employed less than one year and 27% for ten years or more. Statistically significant excesses in mortality were observed for all malignant neoplasms (19 observed, 10.6 expected; standardized mortality ratio [SMR], 180), for neoplasms of the respiratory system (10/3.5; SMR, 290), for bronchogenic cancer (9/3.3; SMR, 270) and for all nonmalignant respiratory disease (8/2.9; SMR, 277). Evidence of an exposure-response relationship was observed by latency for bronchogenic cancer. The authors concluded that tremolite and anthophyllite are the prime suspected etiological factors associated with the observed increase in bronchogenic cancer and nonmalignant respiratory disease in this cohort. No data on smoking were available. A possible confounding factor in this study was previous exposures at other mines in the area; however, exposures to amphibole fibre in all these regional talc operations were reported to be substantially the same.

Stille and Tabershaw (1982) conducted a cohort mortality study on the same mine and mill studied by Brown *et al.* (1979). The composition of their cohorts was somewhat different, the current study including 655 employees who had ever worked for the company between 1 January 1948 and 31 December 1977, after exclusion of 35 women office workers and 53 workers for whom birth dates or other significant data were not available. Cause-specific mortality rates were based on 113 deaths as of December 1978. The SMR for all sites of cancer was 122 (25 observed/20.5 expected); 11 cases were respiratory cancers, and ten of those were lung cancer, with SMRs of 163 and 157, respectively. The cohort was then divided according to whether an individual had been employed elsewhere before coming to work at the particular mine and mill under investigation. Those few who had worked only at the company in question were found to have very low mortality from lung cancer (two observed, 2.6 expected). [The Working Group noted a number of methodological problems, including selection bias, lack of statistical testing, small numbers of person-years of exposure, and no analysis with respect to exposure.]

Rubino *et al.* (1976) studied 1514 miners and 478 millers employed for at least one year between 1921 and 1950 in talc mines and mills in the Germanasca and Chisone valleys

(Piedmont) in Italy. The talc in those mines is described as quite pure, with only some tremolite microinclusions; no other fibrous mineral was reportedly found. [Further details of the exposure are reported in section 2.2(b).] Significant increases in specific cause of death among miners were found for silicosis (62 observed/30.9 expected) and for silico-tuberculosis (18/9.1). Significant deficits in cause-specific mortality were reported for malignant neoplasms (100/129.5), malignant neoplasms of the lung, bronchus and trachea (9/19.7) and malignant neoplasms at other sites (23/39.9). Two cases of pleural mesothelioma and a high occurrence of silicosis and silico-tuberculosis were found in the comparison group. [The Working Group noted that the method used to derive the number of expected deaths is not adequately described. It was considered that the lack of comparability between the worker and comparison groups could be the main explanation for the mortality increases and deficits observed in this study.]

Selevan *et al.* (1979) carried out a study of talc exposures in five companies (two of which ceased operations in 1952 and 1960) in three regions in Vermont, USA. Analysis of airborne dust samples and talc bulk samples revealed no asbestos, either by X-ray diffraction or analytical electron microscopy. Levels of respirable free silica were below 0.25% in nearly all ore and product samples, and free silica was only occasionally detectable in air samples. Insufficient information was available to estimate cumulative exposures, but the authors stated that past exposure levels for miners and millers far exceeded the present standard for nonfibrous talc of 20 mppcf. They considered it probable that dust exposures for millers were higher than those for miners. In one mine, which had closed by the time of the study, 'cobblestones' of highly tremolitic serpentine rock were present but were avoided or discarded as far as possible prior to milling. The cohort consisted of all white male talc workers who had been radiographed as part of annual voluntary surveys of the Vermont Health Department, who were employed in the Vermont talc industry between 1 January 1940 and 31 December 1969, and who had worked in the industry for at least one year. [Because of the voluntary nature of the survey, the cohort may not have been representative (Davis *et al.*, 1983).] There were 90 deaths among the 392 members of this cohort; vital status was not established for four. For nonmalignant respiratory disease and respiratory cancer, Vermont rates were used for comparison, because they are higher than national rates; for other causes of death, US rates were used. [The Working Group noted this unconventional analytical approach.] While some increase was noted for malignant neoplasms, and specifically for respiratory neoplasms (6 observed/3.69 expected), these were not found to be significant. [The Working Group noted that the results were not analysed by latency.] The excess of respiratory cancer occurred only among miners (5/1.15; $p < 0.05$), and the significant excess for nonmalignant respiratory disease occurred only among millers (7/1.72; $p < 0.01$). Most of those dying with nonmalignant respiratory disease had radiographic evidence of pneumoconiosis (rounded opacities). Miners were also exposed to radon daughters at mean levels ranging up to 0.12 working levels, with single peaks of 1.0 working level. [The Working Group noted that no data on smoking were available.]

In a short communication, Léophonte *et al.* (1983) reported on the mortality of talc workers in Luzenac, France. The talc in this region is said to contain no asbestos and levels of quartz varying from 0.5 to 3%. The cohort comprised those who left employment between

1 January 1945 and 31 December 1981 having worked for at least one year. Of 470 workers available for study, 256 were living, 209 had died and five were lost to follow-up; 192/204 with known occupational exposure had worked only at Luzenac. When compared with the regional population, the median age of death was not found to be influenced by dust exposure. There was no significant excess in cancer mortality in general, and, specifically, mortality from respiratory and digestive cancers was not increased. A significant increase in mortality was found for nonmalignant respiratory disease, especially for pneumoconiosis and obstructive lung disease. [The Working Group noted the unconventional definition of the cohort, that no data on smoking habits were available, and that causes of death were obtained for cases from local doctors, hospitals or families but for controls from regional or national records.]

Katsnelson and Mokronosova (1979) reported a study of mortality among workers in a talc mining and processing plant in the USSR. Very high mortality ratios were found. [The Working Group noted that the deaths observed among exposed workers included current and past workers but that the denominator comprised only currently employed persons.]

It has been suggested on the basis of ecological studies that the practice of coating rice with talc, which may be contaminated with asbestos, may play a causal role in the relatively high rate of stomach cancer in Japan (Merliss, 1971a,b; Blejer & Arlon, 1973; Matsudo *et al.*, 1974); however, this hypothesis has not been supported by case-control studies.

Cramer *et al.* (1982) reported a case-control study of ovarian cancer and talc exposure in the Boston, Massachusetts, USA, area between November 1978 and September 1981. Two-hundred-and-fifteen women with pathologically-confirmed epithelial ovarian cancers were identified and matched randomly by residence, race and age. Ninety-two (42.8%) cases regularly used talc either as a dusting powder on the perineum or on sanitary napkins compared with 61 (28.4%) controls. Adjusted for parity and menopausal status, this difference yields a relative risk of 1.9 ($p < 0.003$). Women who had regularly engaged in both practices had an adjusted relative risk of 3.3 ($p < 0.001$) compared to women with neither exposure. [The Working Group noted that while this study suggests an association between talc use and ovarian cancer, information was not available regarding the asbestos content of the talcs, levels of exposure or whether the interviews were conducted by people who were unaware of the case referent status of the person being interviewed.]

4. Summary of Data Reported and Evaluation

4.1 Exposure data

Talc occurs in various geological settings around the world but is usually formed by alteration of ultramafic rocks or dolomites. Talc deposits may contain various other minerals, including carbonates, free silica and serpentines (including chrysotile) and amphibole minerals (asbestiform and nonasbestiform). Occupational exposures occur during mining, milling, processing and in a wide variety of secondary industries (e.g.,

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ceramics, paper, rubber and paint production). Exposure of the general population occurs through use of products such as cosmetics.

4.2 Experimental data

Talc of different grades was tested for carcinogenicity in mice by subcutaneous, intraperitoneal and intrathoracic injection, in rats by oral administration, inhalation exposure and intraperitoneal, intrathoracic and intrapleural injection, and in hamsters by inhalation exposure and intratracheal instillation. The majority of these studies were inadequate. Tumour incidence was not increased following either the administration of single doses of various talcs to rats by intrapleural administration or administration of talc by four intraperitoneal injections. A single subcutaneous injection of talc in mice did not produce local tumours. No tumour was produced by administration of talc in the diet of rats. In most of the above studies, characterization of the talc was insufficient to determine whether it contained asbestiform fibres.

No teratogenic effect was observed in rats, mice, hamsters or rabbits following oral administration of talc.

Talc was not mutagenic to *Salmonella typhimurium* or *Saccharomyces cerevisiae* in host-mediated assays. It did not induce chromosomal aberrations in cultured human cells or in rats *in vivo* or dominant lethal mutations in rats.

Overall assessment of data from short-term tests: Talc^a

	Genetic activity			Cell transformation
	DNA damage	Mutation	Chromosomal effects	
Prokaryotes		—		
Fungi/ Green plants		—		
Insects				
Mammalian cells (<i>in vitro</i>)			—	
Mammals (<i>in vivo</i>)			—	
Humans (<i>in vivo</i>)				
Degree of evidence in short-term tests for genetic activity: Inadequate				Cell transformation: No data

^aThe groups into which the table is divided and the symbol '—' are defined on pp. 19-20 of the Preamble; the degrees of evidence are defined on pp. 20-21.

4.3 Human data

Case reports have suggested an association between exposure to talc containing asbestiform fibres and mesothelioma.

Proportionate mortality studies of miners and millers of talc containing asbestiform tremolite and anthophyllite showed an excess of lung cancer and one case of mesothelioma. A cohort study of workers in one company revealed significant excess mortality from lung cancer and from nonmalignant respiratory disease. Mortality from lung cancer increased with latency.

In several mortality studies, cancer risk was assessed among miners and millers of talc that was reported to contain no more than trace amounts of asbestiform minerals. A cohort mortality study of talc miners and millers showed an excess of lung cancer in underground miners but not in millers; a contributory etiological role of radon daughters to the lung cancer risk in miners could not be excluded. Three other studies suffered from methodological limitations and could not be interpreted.

A case-control study suggested an approximate doubling of the risk for ovarian cancer among women after perineal use of talc.

4.4 Evaluation¹

There is *inadequate evidence* for the carcinogenicity of talc to experimental animals.

There is *inadequate evidence* for the carcinogenicity to humans of talc not containing asbestiform fibres, while there is *sufficient evidence* for the carcinogenicity to humans of talc containing asbestiform fibres.

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¹For definition of the italicized terms, see Preamble, pp. 18 and 22.

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Exhibit 86

to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food. Third, these amendments to this health claim will ensure that scientifically sound nutritional and health information regarding the benefits of fruit and vegetable intake and reduction of CHD risk can be provided to consumers as soon as possible. The past few editions of the DGA have been moving away from a focus on total fat and have instead communicated to consumers the need to focus on type of fat consumed instead of total amount of fat. Recent editions of the DGA have also encouraged increased intake of fruits and vegetables for a healthful diet. Prompt issuance of an interim final rule that reflects the current recommendations is necessary for consumers to be able to have the most current information on nutrition and diet. Consumers will be better able to construct healthful diets if they have prompt access to information that is consistent with the current recommendations on fat content and on consumption of fruits and vegetables. Therefore, we are using the authority in section 403(r)(7)(A) of the FD&C Act to issue an interim final rule amending the general requirements for the health claim for dietary saturated fat and cholesterol and risk of CHD and to make the interim final rule effective immediately.

This regulation is effective upon publication in the **Federal Register**. We invite public comment on this interim final rule. We will consider modifications to this interim final rule based on comments made during the comment period. We will address comments and confirm or amend the interim final rule in a final rule.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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9. FDA/CFSAN, Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease, Regulatory Impact Analysis, FDA–2013–P–0047.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

- 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

- 2. Section 101.75 is amended by revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

* * * * *

(c) * * *

(1) All requirements set forth in § 101.14 shall be met, except § 101.14(e)(6) with respect to a raw fruit or vegetable.

(2) * * *

(ii) *Nature of the food.* (A) The food shall meet all of the nutrient content requirements of § 101.62 for a "low saturated fat" and "low cholesterol" food.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food, unless it is a raw fruit or vegetable; except that fish and game meats (*i.e.*, deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in § 101.62.

* * * * *

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29997 Filed 12–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 878, 880, and 895

[Docket No. FDA–2015–N–5017]

RIN 0910–AH02

Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is banning these devices.

DATES: This rule is effective on January 18, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the

heading of this final rule into the "Search" box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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I. Executive Summary

A. Purpose and Coverage of the Final Rule

Medical gloves play a significant role in the protection of both patients and health care personnel in the United States. Health care personnel rely on medical gloves as barriers against transmission of infectious diseases and contaminants when conducting surgery, as well as when conducting more limited interactions with patients. Various types of powder have been used to lubricate gloves so that wearers could don the gloves more easily. However, the use of powder on medical gloves presents numerous risks to patients and health care workers, including inflammation, granulomas, and respiratory allergic reactions.

A thorough review of all currently available information supports FDA's

conclusion that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove should be banned. FDA has concluded that the risks posed by powdered gloves, including health care worker and patient sensitization to natural rubber latex (NRL) allergens, surgical complications related to peritoneal adhesions, and other adverse health events not necessarily related to surgery, such as inflammatory responses to glove powder, are important, material, and significant in relation to the benefit to public health from their continued marketing. FDA has carefully evaluated the risks and benefits of powdered gloves and the risks and benefits of the state of the art, which includes viable non-powdered alternatives that do not carry any of the risks associated with glove powder, and has determined that the risk of illness or injury posed by powdered gloves is unreasonable and substantial. Further, FDA believes that this ban would likely have minimal economic and shortage impact on the health care industry. Thus, a transition to alternatives in the marketplace should not result in any detriment to public health.

This rule applies to powdered patient examination gloves, powdered surgeon's gloves, and absorbable powder for lubricating a surgeon's glove. This includes all powdered medical gloves except powdered radiographic protection gloves. Because we are not aware of any powdered radiographic protection gloves that are currently on the market, FDA lacks the evidence to determine whether the banning standard would be met for this particular device. The ban does not apply to powder used in the manufacturing process (e.g., former-release powder) of non-powdered gloves, where that powder is not intended to be part of the final finished glove. Finished non-powdered gloves are expected to include no more than trace amounts of residual powder from these processes, and the Agency encourages manufacturers to ensure finished non-powdered gloves have as little powder as possible. In our 2008 Medical Glove Guidance Manual (Ref. 1), we recommended that non-powdered gloves have no more than 2 milligrams (mg) of residual powder and debris per glove, as determined by the Association for Testing and Materials (ASTM) D6124 test method (Ref. 2). The Agency continues to believe this amount is an appropriate maximum level of residual powder. The ban also does not apply to powder intended for use in or on other

medical devices, such as condoms. FDA has not seen evidence that powder intended for use in or on other medical devices, such as condoms, presents the same public health risks as that on powdered medical gloves.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves, (2) powdered patient examination gloves, and (3) absorbable powder for lubricating a surgeon's glove. Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for patient examination and surgeon's gloves will apply only to non-powdered gloves while the powdered version of each type of glove will be added to the listing of banned devices in the regulations.

Many comments requested that FDA revise the scope of the ban to include all NRL gloves. Many comments from industry requested that the proposed effective date be extended beyond 30 days after the date of publication of the final rule. Of the comments that do not support the ban, commenters noted the need for powdered gloves to aid in donning gloves and tactile sense and the reduced risks associated with current powdered gloves that have less powder. The remaining comments are not clearly in support or opposition to the proposal.

C. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends 21 CFR 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

D. Costs and Benefits

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society, but is expected to reduce the number of adverse events associated with using powdered gloves. The primary public health benefit from adoption of the rule would be the value of the reduction in adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between \$26.8 million and \$31.8 million.

II. Background

A. Need for the Regulation/History of the Rulemaking

On March 22, 2016, FDA issued a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 15173). Section 516(a)(1) of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device "presents substantial deception or an unreasonable and substantial risk of illness or injury." For a more detailed discussion of the banning standard, we refer you to the preamble of the proposed rule. FDA issued the proposed regulation because it determined that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling.

The preamble to the proposed rule describes the history of powdered gloves and the citizen petitions received by the Agency that request a ban on powdered gloves. We refer readers to that preamble for information about the development of the proposed rule. The level and types of risk presented by powdered gloves varies depending on the composition and intended use of the glove. In aggregate, the risks of powdered gloves include severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. We refer readers to the preamble of the proposed rule for details on the level and types of risks presented by powdered gloves. The benefits of powdered gloves appear to only include greater ease of donning

and doffing, decreased tackiness, and a degree of added comfort, which FDA believes are nominal when compared to the risks posed by these devices.

The state of the art of both surgeon's and patient examination gloves includes non-powdered alternatives that provide similar performance as the various powdered glove types do. That is, there are many non-powdered gloves available that have the same level of protection, dexterity, and performance. Thus, based on a careful evaluation of the risks and benefits of powdered gloves and the risks and benefits of the current state of the art, which includes readily available alternatives that carry none of the risks posed by powdered gloves, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban.

Finally, as discussed in the proposed rule, FDA also determined the ban should apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as to devices that would be sold or distributed in the future (see 21 CFR 895.21(d)(7)). This means that powdered gloves currently being used in the marketplace would be subject to this ban and adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), and thus subject to enforcement action.

B. Summary of Comments to the Proposed Rule

The Agency requested public comments on the proposed rule, and the comment period closed on June 20, 2016. The Agency received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule. See Section IV for the description of comments on the proposed rule and FDA's responses.

C. General Overview of the Final Rule

FDA published a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, because FDA

determined that these devices present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling (81 FR 15173).

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves (21 CFR 878.4460), (2) powdered patient examination gloves (21 CFR 880.6250), and (3) absorbable powder for lubricating a surgeon's glove (21 CFR 878.4480). Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for surgeon's gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) will apply only to non-powdered gloves while the powdered version of each type of glove will be added to 21 CFR part 895, subpart B—Listing of Banned Devices.

D. Clarifying Changes to the Rule

While FDA believes that the preamble to the proposed rule was clear that the proposed ban would apply to all powdered surgeon's gloves and all powdered patient examination gloves, in reviewing the terminology used in the proposed additions to 21 CFR part 895, FDA determined that term "synthetic latex" would not cover every type of non-NRL material that is used to manufacture powdered gloves. It was not FDA's intent to limit the ban to only powdered NRL and powdered synthetic latex gloves, and we believe that this intent was clear from the content of the preamble to the proposed rule, which stated that the ban "would apply to all powdered gloves except powdered radiographic protection gloves." As such, FDA has now revised the identification in this final rule to clarify that the ban applies to all powdered surgeon's gloves and powdered patient examination gloves without reference to the type of material from which they are made. Additionally, the identification of non-powdered surgeon's gloves and non-powdered patient examination gloves is also being revised to remove reference to material.

III. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as medical devices under section 201(h) of the FD&C Act (21 U.S.C. 321). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device

presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

IV. Comments on the Proposed Rule and FDA's Responses

A. Introduction

We received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule.

We describe and respond to the comments in section IV.B through E. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Many comments support the proposed ban on powdered patient examination gloves and powdered surgeon's gloves. These comments from individual consumers, health care professionals, academia, and industry highlight several risks of the continued use of powdered gloves, including, among others, allergic reactions, post-

operative adhesions, and delayed wound healing.

(Response 1) FDA agrees with these comments. After further review of all available information and the comments submitted to the proposed rule, FDA has concluded that the public's exposure to the risks of powdered gloves is unreasonable and substantial in relation to the nominal public health benefit derived from the continued marketing of these devices, especially when considering the benefits and risks posed by readily available alternative devices. Therefore, FDA has determined that the standard for a ban on these devices has been met.

C. Description of Comments That Oppose the Regulation and FDA Response

FDA received some comments that oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves for various reasons. We address each of these reasons for opposition in this section. After reviewing these comments, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban. We are finalizing the ban with only clarifying changes.

(Comment 2) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning or doffing non-powdered gloves. Two commenters specifically discuss hyperhidrosis with claims that it can add to the difficulty donning and doffing non-powdered gloves. One commenter has asserted that double-gloving is more difficult when using non-powdered gloves.

(Response 2) As described in the preamble of the proposed rule, we have concluded that the benefit of ease of donning or doffing powdered gloves is generally nominal (Ref. 3) in comparison to the risks posed by the continued marketing of powdered gloves, which, among others, include severe airway inflammation, hypersensitivity reactions, and allergic reactions (including asthma). Also, as noted in the proposed rule, a study of various brands of powdered and non-powdered NRL gloves by Cote et al. found that there are non-powdered latex gloves that are easily donned with wet or dry hands with relatively low force compared to the forces required to don powdered latex examination gloves (Ref. 3). Thus, FDA has considered ease of donning and doffing as a benefit as it applies within the banning standard, and has determined that the standard is met.

(Comment 3) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning non-powdered gloves, leading to greater propensity of non-powdered gloves to tear. Some of these comments express concern that the reduced ability to separate the opening of a non-powdered glove or the greater propensity of non-powdered gloves to tear could potentially lead to a higher degree of contamination and post-procedure infections.

(Response 3) FDA disagrees with the assertion that non-powdered gloves have a higher propensity to tear and thus disagrees that use of non-powdered gloves presents a greater risk of contamination, post-procedure infections, or exposure of the user to blood. FDA does not believe there is compelling evidence to support the assertion that non-powdered gloves have a higher propensity to tear. Korniewicz, et al., determined that the presence of powder did not affect the durability of gloves or enhance glove donning (Ref. 4). Although Kerr, et al., identified a statistically significant difference in the durability of non-powdered vinyl gloves compared to powdered vinyl gloves, this difference may be attributed to glove type, manufacturer, and the fingernail length of users rather than the presence or absence of powder (Ref. 5). This study also found that vinyl gloves in general are less durable and have a greater propensity to tear compared to nitrile, neoprene, and latex gloves. Furthermore, as discussed in the response to comment 4, several studies have found that alternatives to non-powdered NRL gloves, such as nitrile and neoprene gloves, offer the same level of protection against contamination and exposure to blood as powdered NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Therefore, FDA has determined that suitable alternatives to powdered gloves are readily available in the marketplace.

(Comment 4) Commenters oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because the fit of powdered gloves is more comfortable than non-powdered gloves. Some of these comments assert that the reduced fit of non-powdered gloves inhibits the tactile sensation necessary to perform medical procedures.

(Response 4) FDA disagrees with the assertion that non-powdered gloves inhibit the tactile sensation necessary to perform medical procedures. The ban does not include non-powdered NRL gloves, which offer the same

performance characteristics of powdered NRL gloves, and several studies have found that alternatives, such as nitrile and neoprene gloves, offer the same level of protection, dexterity, and performance as NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Furthermore, the numerous risks posed by the continued marketing of powdered gloves outweigh the benefit of whatever additional level of comfort is provided from using powdered gloves instead of the non-powdered alternatives that carry none of these risks.

(Comment 5) Some comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, citing a lack of scientific evidence that gloves with reduced powder content, as those in use today, have the same risks as previously used gloves that had higher powder content.

(Response 5) FDA agrees that the maximum residual level of powder on powdered gloves is less than earlier types of powdered gloves. Historically, powdered medical gloves contained powder levels ranging from 50 to over 400 mg of powder per glove. Effective in 2002, the ASTM International recommended limits on powder levels is 15 mg per square decimeter for surgical gloves (ASTM D3577–2001) (Ref. 11) and 10 mg per square decimeter for patient examination gloves (ASTM D3578) (Ref. 12). As a result, FDA believes that gloves in use after 2002 follow these recommended limits and generally have lower powder content than earlier types of powdered gloves. Even so, several studies indicate that gloves with reduced powder levels continue to present unreasonable and substantial risks to patients and health care workers. For instance, a study conducted on the incidence of skin reactions for Greek endodontists from 2006 to 2012 found that glove powder accounted for the majority of skin reactions, and the replacement of powdered NRL gloves with non-powdered gloves resolved the majority of the adverse reactions (Ref. 13). Similarly, the risks of powdered gloves persist in non-clinical studies using gloves with reduced powder content, as demonstrated by the 2013 finding that surgeries performed with powdered gloves increased the number, density, and fibrotic properties of peritoneal adhesions in rats compared with surgeries performed with non-powdered gloves (Ref. 14). Also, the reduction in cases of NRL-induced occupational contact urticaria coincided with French hospitals transitioning to non-powdered gloves after 2004–2005 (Ref. 13).

Finally, FDA is not aware of any report in the literature that supports the assertion that currently marketed powdered gloves with lower powder content reduce the risks presented by powdered gloves (Ref. 15). In summary, FDA concludes that the risks of powder continue to be unreasonable and substantial for currently marketed powdered gloves despite lower powder content than previous generations of powdered gloves.

(Comment 6) Two comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the commenters believe a warning on the risks of powdered gloves is sufficient to mitigate the risks posed by these devices.

(Response 6) As described in Section IV of the proposed rule, FDA has determined that no change in labeling could correct the risk of illness or injury presented by the continued use of these devices. Powdered gloves have additional or increased risks to health compared to non-powdered gloves related to the spread of powder, and the fact that powder-transported contaminants such as NRL allergens can become aerosolized. Exposure to powder or latex allergens presents significant risks to health care workers and patients when inhaled or when exposed to internal tissue during oral, vaginal, gynecological, and rectal exams. Although labeling can raise awareness of these risks, we conclude that labeling cannot effectively mitigate these risks because it cannot prohibit the spread of glove powder or powder-transported contaminants. In addition, an important aspect of these devices is their ability to affect persons other than the individual who decides to wear or use them. For example, patients often do not know the type of gloves being worn by the health care professional treating them, but are still exposed to the potential dangers. Similarly, glove powder's ability to aerosolize and carry NRL proteins exposes individuals to harm via inhalation or surface contact. Thus, some of the risks posed by glove powder can impact persons completely unaware or unassociated with its employment and without the opportunity to consider the devices' labeling. Because of this inherent quality, adequate directions for use or warnings cannot be written that would provide reasonable assurance of the safe and effective use of these devices for all persons that might come in contact with them.

Due to the ability of powder to affect people who would not have an opportunity to read warning labels, and

because potential warning labels would raise awareness of the risks, but would not eliminate the risks posed by glove powder, FDA has determined no label or warning can correct the risks posed by these devices.

(Comment 7) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the solvent used to remove powder during the manufacture of non-powdered gloves may cause adverse reactions to the glove user.

(Response 7) FDA is not aware of any report in the literature that supports the assertion of widespread adverse reactions to solvent used in the manufacturing process. Non-powdered patient examination and surgeon's gloves require premarket notification (510(k)) submissions prior to marketing. During the review of these submissions, FDA evaluates the final finished glove, including manufacturing solvents that are present on the final glove. FDA recommends that manufacturers conduct and submit skin irritation and dermal sensitization studies in these submissions to evaluate potential issues with components, including manufacturing solvents (Ref. 1). Although individual hypersensitivity reactions to different materials may occur, FDA has been unable to find evidence in the literature of hypersensitivity to typical glove manufacturing materials other than glove powder or NRL. However, Palosuo, et al., reports that the use of hand sanitizers containing isopropyl alcohol prior to donning gloves could cause dermatitis reaction if the gloves are donned before the alcohol dries (Ref. 16). The occurrence of this reaction is unrelated to the manufacture of non-powdered gloves and unrelated to the use of non-powdered gloves as an alternative to powdered gloves. Given the lack of evidence of adverse reactions to solvents used in the manufacturing of non-powdered gloves, and the established evidence demonstrating the risks of powdered glove use, FDA continues to believe that powdered gloves and glove powder meet the banning standard.

(Comment 8) Several comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves due to the expectation that users will ultimately have to pay more for medical gloves once the ban is finalized, because the cost of non-powdered gloves is currently higher than the cost of powdered gloves.

(Response 8) We do not find any evidence to support the claims that

current prices of non-powdered gloves are significantly higher than powdered gloves. As we stated in the preliminary regulatory impact analysis (PRIA), extensive searches of glove distributor pricing indicate that non-powdered gloves have become as affordable as powdered gloves. Our searches also revealed that the market is saturated with alternatives to powdered gloves, resulting in downward pressure on the prices of non-powdered gloves. In addition, the share of powdered medical gloves sales has been declining since at least 2000 while total sales of all disposable medical gloves have increased (Ref. 17). We would not expect this trend to be occurring without regulatory action if users of disposable medical gloves faced significantly higher prices for switching to non-powdered gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 9) We received one comment that disagrees with our determination that the availability of examination and surgical gloves would not be reduced.

(Response 9) We do not find any evidence to support these claims. As we stated in the PRIA, research shows only 7 percent of total sales of examination and surgical gloves to medical workers were projected to be from powdered gloves in 2010 (Ref. 17). Global Industry Analysts (GIA) projected the share of powdered disposable medical gloves sales to decrease to 2 percent in 2015, while total sales of all disposable medical gloves continue to increase (Ref. 17). We would not expect this trend to be occurring without regulatory action if there were a reduction in the availability of disposable examination and surgical gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 10) Commenters suggest there would be a loss in consumer utility due to the preference some medical workers may have for powdered gloves due to comfort and ease of use.

(Response 10) We stated in the PRIA that the remaining 7 percent continuing to use these powdered gloves may experience utility loss from the removal of powdered gloves from the market (Ref. 17). The potential loss in consumer utility would be due to the perceived loss in comfort from powdered gloves users switching to non-powdered gloves. However, as the GIA report shows, there has been a downward trend in total sales of powdered gloves since at least the year 2000 while total sales of all disposable medical gloves has increased (Ref. 17). We would not

expect this trend to be occurring without regulatory action if the loss in consumer utility to current medical workers were substantial. Korniewicz et al. reported no loss in consumer satisfaction in a sample of operating room staff switching to non-powdered surgical gloves (Ref. 4). We have not estimated this potential burden, but the evidence described here suggests that any burden would not be substantial. Further, even having considered that some degree of consumer comfort may be lost by banning powdered gloves, FDA continues to believe that this benefit is considerably outweighed by the numerous risks posed by powdered gloves.

(Comment 11) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the risks identified for powdered gloves are due to contaminants, such as pesticides and herbicides, in the powder that would not be present if the powder were manufactured in the United States.

(Response 11) FDA disagrees with the assertion that contaminated powder is the source of the risks identified for powdered gloves. FDA's proposal to ban powdered gloves and glove powder is based on various studies on the risks of powdered gloves due to the properties of the powder itself. Powdered gloves have additional or increased risks to health compared to non-powdered gloves. For example, powder on NRL gloves can aerosolize latex allergens, resulting in sensitization to latex and allergic reactions. Latex sensitization and allergic reactions are unrelated to any potential presence of manufacturing contaminants, such as pesticides and herbicides. Additional risks of powdered gloves include severe airway inflammation, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. FDA's assessment of the available literature and information indicates that these risks are attributable to the powder itself, as opposed to any potential presence of manufacturing contaminants, such as pesticides and herbicides.

In addition, the powder used on powdered gloves is required to comply with FDA's Quality System regulation, which includes requirements for quality and inspection for the final finished gloves that protect against the introduction of contaminated devices into commerce. Among other requirements, device manufacturers must establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an

adverse effect on product quality (21 CFR 820.70(e)). FDA's Quality System regulation applies to gloves and glove powder sold in the United States, regardless of the manufacturing location.

D. Description of Comments on Scope of Ban and FDA Response

FDA received several comments requesting revision of the scope of the ban. The scope of the proposed ban includes powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove. The glove types include all powdered patient examination and surgeon's gloves, including NRL and synthetic latex gloves. In the following paragraphs, we discuss and respond to comments requesting revision of the scope of the ban. We are finalizing the ban without change to the scope, but clarifying that all powdered patient examination gloves and powder surgical gloves are banned, regardless of the material from which they are made.

(Comment 12) Several comments identify risks that result from the use of powdered and non-powdered NRL gloves. These comments request FDA to extend the ban to all NRL gloves, both powdered and non-powdered.

(Response 12) Unlike with powdered latex gloves, which have the ability to aerosolize glove powder and carry allergenic proteins, FDA believes the risk of allergic reaction to non-powdered NRL gloves, which affects the user and patients in direct contact with the glove, is adequately mitigated through already-required labeling that alerts users to this risk. NRL gloves must include a statement to alert users to the risk of allergic reactions caused by NRL (21 CFR 801.437). Further, several studies have indicated that the use of non-powdered NRL gloves reduces the risk of sensitization to allergenic NRL proteins and the number of allergic reactions experienced by those who are already sensitized (Refs. 18, 19, and 20). FDA believes that these study results, when considered alongside the risk mitigation that follows from FDA's required labeling for NRL products, demonstrates that non-powdered latex gloves can be safely used with appropriate caution for latex-sensitive patients and health care workers. Therefore, FDA has determined not to ban the use of all NRL gloves.

(Comment 13) Several comments raise the issue of life threatening latex allergy events that result from various uses of NRL gloves including food preparation and food service. Several of these comments assert that the Agency should broaden the scope of the ban to cover all

NRL gloves for all uses including food preparation and food service.

(Response 13) We have concluded that it is not appropriate to address a proposal to ban gloves used for food preparation because these gloves do not meet the definition of a device under section 201(h) of the FD&C Act and are thus not subject to section 516 of the FD&C Act (21 U.S.C. 360f), which provides the statutory authority to ban devices within FDA's authority to regulate such products.

(Comment 14) One comment asserts that the ban on powdered gloves should not apply to dental practice, because the risks are not applicable to dental practice.

(Response 14) FDA disagrees with the assertion that the risks of powdered gloves are not applicable to dental practice. Dentists and dental patients face the same risks as other medical practices in terms of the potential for powder exposure to open cavities or open wounds, and for powder, if used with NRL gloves, to carry protein allergens. Several studies documenting the risks of powdered gloves in dental practices have been conducted, including Saary, et al., which identified that changing to low-protein and non-powdered NRL gloves reduced NRL allergy in dental students (Ref. 18). In addition, Charous et al., reported in 2000 that a dental office was able to reduce airborne NRL antigen levels to undetectable levels with the exclusive use of non-powdered NRL gloves, permitting a highly sensitized staff member to continue to work there (Ref. 21). These studies, among others (Refs. 13 and 22), indicate that the risks of powdered medical gloves apply to dental practice. Therefore, FDA has determined that the scope of the ban on powdered medical gloves should continue to include powdered gloves used in dental practice.

E. Description of Other Specific Comments and FDA Response

Many comments made specific remarks requesting clarification or revision to the proposed rule. In the following paragraphs, we discuss and respond to such specific comments.

(Comment 15) A number of comments request extension of the effective date of the ban. The proposed rule included a proposed effective date of 30 days after publication of the final rule for all devices, including those already in commercial distribution. The comments suggest a range of effective dates of 90 days to 18 months after publication of the final rule and assert that a longer transition period is necessary to allow

existing inventory to flow through the supply chain to providers and patients.

(Response 15) FDA is not extending the effective date of the ban for devices already in commercial distribution. We have concluded that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. The continued marketing of these devices beyond the 30 day effective date would allow for the continued sale and purchase of devices that FDA has determined present an unreasonable and substantial risk to patients and health care workers. Therefore, FDA does not believe that it is in the best interest of the public health to extend the effective date for devices already in commercial distribution. In order to minimize the risk of continued exposure of health care workers and patients to these devices, the effective date for devices remains 30 days after the date of publication of this final rule.

(Comment 16) One comment requests that FDA not extend the effective date of the ban to allow companies to deplete their inventory of the devices.

(Response 16) As described in the response to comment 15, FDA agrees that it is in the best interest of the public health to not extend the effective date of the ban for devices already in commercial distribution. Therefore, the effective date of the ban for devices already in commercial distribution remains at 30 days after the date of publication of the final rule.

(Comment 17) A few comments request recommendations on the means of disposal or recycling of powdered gloves.

(Response 17) FDA recommends that unused inventories of powdered medical gloves remaining at domestic manufacturing and distribution locations be disposed of in accordance with standard industry practices. Unused supplies at hospitals, outpatient centers, clinics, medical and dental offices, other service delivery points (nursing homes, etc.), and in the possession of end users, will need to be disposed of according to established procedures of the local community's solid waste management system. Established procedures for these materials typically involve disposal in landfills or incineration. FDA has concluded that this final rule will not have a significant impact on the human environment. (See Section VII. Analysis of Environmental Impact.)

(Comment 18) One comment requests clarification on whether after the effective date of the ban the Agency will permit a manufacturer to export powdered medical gloves that are already physically located at distribution centers in the United States.

(Response 18) After the effective date of this final rule, manufacturers will not be allowed to import powdered medical gloves. However, while powdered medical gloves will be banned in the United States on the effective date of this final rule, manufacturers may export existing inventory of powdered gloves to a foreign country if the device complies with the laws of that country and has valid marketing authorization by the appropriate authority, as described in section 802 of the FD&C Act (21 U.S.C. 382)). If eligible for export under section 802 of the FD&C Act, a device intended for export will not be deemed adulterated or misbranded if it

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

V. Effective Date

This rule is effective January 18, 2017. The effective date of this rule applies to devices already in commercial distribution and those already sold to the ultimate user, as well as to devices that would be sold or distributed in the future. All powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves must be removed from the market upon the effective date of this final rule. Section 501(g) of the FD&C Act (21 U.S.C. 351(g)) deems a device to be adulterated if it is a banned device.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety,

and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule prohibits marketing of powdered surgeon’s gloves, powdered patient examination gloves, and absorbable powder for lubricating surgeon’s gloves. The rule does not cover or include powdered radiographic gloves.

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society. Extensive searches of glove distributor pricing indicate that improvements to non-powdered gloves have made these products as affordable as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between \$26.8 million and \$31.8 million. The present discounted value of the estimated benefits over 10 years ranges from \$228.9 million to \$270.8 million at a 3 percent discount rate and from \$188.5 million to \$223 million at a 7 percent discount rate.

FDA has examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small

entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule will not impose any new burdens on small entities, and thus will not impose a significant economic impact on a substantial number of small entities.

The full discussion of the economic impacts of the rule, which includes a list of changes made in the final regulatory impact analysis, in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at <https://www.regulations.gov> under the docket number (FDA–2015–N–5017) for this rule and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#> (Ref. 23).

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this final rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused powdered surgeon’s gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon’s glove that will need to be handled after the rule is finalized.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste at municipal solid waste (MSW) facilities nationwide. The selected action, if finalized, will result in an initial batch disposal of unused powdered surgeon’s gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon’s glove from user facilities to MSW facilities nationwide, followed by a rapid decrease in the rate of disposal of these devices, as supplies are depleted. The selected action does not change the ultimate disposition of these devices but expedites their rate of disposal and ceases future production. Overall, given the limited number of powdered surgeon’s gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon’s glove, currently in commercial distribution, the selected action is expected to have no significant impact on MSW and landfill facilities and the environment in affected communities.

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency’s finding of no significant impact and the evidence supporting that finding, contained in an EA, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday (Ref. 24).

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, FDA is not required to seek clearance by Office of Management and Budget under the Paperwork Reduction Act of 1995.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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List of Subjects

21 CFR Parts 878 and 880

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 878, 880, and 895 are amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 878.4460 by revising the section heading and paragraph (a) to read as follows:

§ 878.4460 Non-powdered surgeon's glove.

(a) *Identification.* A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

§ 878.4480 [Removed]

■ 3. Remove § 878.4480.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 4. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 5. Amend § 880.6250 by revising the section heading and paragraph (a) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

(a) *Identification.* A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

PART 895—BANNED DEVICES

■ 6. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 7. Add § 895.102 to read as follows:

§ 895.102 Powdered surgeon's glove.

(a) *Identification.* A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 8. Add § 895.103 to read as follows:

§ 895.103 Powdered patient examination glove.

(a) *Identification.* A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 9. Add § 895.104 to read as follows:

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30382 Filed 12–16–16; 8:45 am]

BILLING CODE 4164–01–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 880**

[Docket No. FDA–2015–N–0701]

**General Hospital and Personal Use
Devices: Renaming of Pediatric
Hospital Bed Classification and
Designation of Special Controls for
Pediatric Medical Crib; Classification
of Medical Bassinet**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also establishing a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. In addition, this rule continues to allow both devices to be exempt from premarket notification and use of the device in traditional health care settings and permits prescription use of pediatric medical cribs and bassinets outside of traditional health care settings.

DATES: This order is effective on January 18, 2017.

FOR FURTHER INFORMATION CONTACT:

Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

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I. Executive Summary

A. Purpose and Coverage of the Final Rule

Pediatric medical cribs that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)) (referred to as pediatric medical cribs or cribs intended for medical purposes) (product code FMS) are regulated by FDA and will have to comply with the special controls identified in this rule for pediatric medical cribs. Cribs that do not meet the device definition (referred

to as cribs for non-medical purposes) must meet the Consumer Product Safety Commission's (CPSC's) regulations and guidelines.

In the **Federal Register** of December 28, 2010 (75 FR 81766), the CPSC issued a final rule prohibiting the use of the drop-side rail design for non-medical cribs in consumer households as of June 28, 2011. CPSC's rule established new standards for full-size and non-full-size cribs intended for non-medical purposes, which effectively prohibited the manufacture or sale of cribs intended for non-medical purposes with a drop-side rail design in households, child care facilities, family child care homes, and places of public accommodation. This rule did not affect pediatric medical cribs regulated by FDA, which typically contain a drop-side rail design that includes movable and latchable side and end rails. Although drop-side cribs intended for non-medical purposes are now prohibited, there is still a need for pediatric medical cribs with drop-side rails inside and outside of traditional health care settings. Pediatric medical cribs with drop-side rails are extremely helpful for patient care in hospital settings and even outside of traditional health care settings, such as day care centers caring for infants and children with disabilities, because they allow parents and care givers easy access to children to perform routine and emergency medical procedures, including, but not limited to, cardiopulmonary resuscitation (CPR), blood collection, intravenous (IV) insertion, respiratory care, and skin care. These drop-side rail cribs also make it easier for hospital staff to facilitate safe patient transport and reduce the chance of care giver injury.

Over the last 5 years, FDA has received over 500 adverse event reports, or Medical Device Reports (MDRs), associated with open pediatric medical cribs, through the Agency's Manufacturer and User Facility Device Experience (MAUDE) database. There were adverse event reports of serious injuries, including reports of entrapment, which were predominantly entrapments of extremities (legs or arms). The majority of MDRs for medical cribs were for malfunctions such as drop-side rails not latching or lowering, brakes not holding, wheels or casters breaking, and where applicable, scales not reading correct weights. As a result of the risks to health and need for continued use of pediatric medical cribs in traditional health care settings and non-traditional settings, FDA is revising the identification for § 880.5140 (21 CFR 880.5140) to include only pediatric